AL 10-000-5142

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

April 6, 2010

The Honorable Lisa Jackson
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

Dear Administrator Jackson:

Thank you for appearing before the Committee on Environment and Public Works on December 2, 2009. We appreciate your testimony, and we know that your input will prove valuable as we continue our work on this important topic.

Enclosed are questions that have been submitted by Senators Boxer, Lautenberg, Carper, Cardin, Inhofe and Vitter for the hearing record. Please submit your answers to these questions by COB April 20, 2010 to the attention of Heather Majors, Senate Committee on Environment and Public Works, 410 Dirksen Senate Office Building, Washington, D.C. 20510. In addition, please provide the Committee with a copy of your answers via electronic mail to Heather_Majors@epw.senate.gov. To facilitate the publication of the record, please reproduce the questions with your responses.

Again, thank you for your assistance. Please contact Grant Cope of the Majority Staff at (202) 224-8832, or Rebeckah Adcock of the Minority Staff at (202) 224-6176 with any questions you may have. We look forward to reviewing your answers.

Sincerely,

Barbara Boxer
Chairman

James M. Inhofe
Ranking Member

Environment and Public Works Committee Hearing
December 2, 2009
Follow-Up Questions for Written Submission

Questions for Jackson

Questions from:

Senator Barbara Boxer

1. Do you believe that the main goal in reforming the Toxic Substances Control Act should be used to ensure the protection of public health, including the health of pregnant women and children, in the manufacturing and use of chemicals in the United States?

2. The use of tens of thousands of chemicals in commerce raises the issue of the need to prioritize the review of such chemicals for their safety.

In reforming the Toxic Substances Control Act, could you please describe the importance of ensuring that EPA has the authority to appropriately prioritize chemicals for review using factors that protect public health threats and then environment?

3. Do you believe that efforts to reform the Toxic Substances Control Act should place the burden squarely on industry to provide information that demonstrates the safety of their chemicals?

4. Federal public health and environmental laws provide a floor and not a ceiling for the minimum level of protection required in the United States. This allows States to provide stronger safeguards than federal law, where states choose to create such protections.

Do you believe in the importance of this principle in efforts to reform the Toxic Substances Control Act?

5. The Agency has a number of voluntary programs, including the "High Production Volume" chemical program and the "Chemical Assessment and Management Program."

Could you please describe your thoughts on the adequacy of these programs for protecting public health from dangerous chemical exposures?

Senator Frank R. Lautenberg

1. As you know, I held this hearing to consider the problems with the existing TSCA, and draw lessons from where it has fallen short to guide us in strengthening protection for public health and the environment. If we are thinking about ways to improve those protections, should we prevent the introduction of new PBTs into the stream of commerce?

2. At the hearing, Director Birnbaum testified to the inherent problems with PBT chemicals, which build-up in our bodies and the environment. Those don't lend

themselves to traditional risk assessment. Should we act to reduce exposure to existing PBT chemicals to the extent possible?

3. Are there non-PBT chemicals -- substances like asbestos, formaldehyde, or hex chrome -- for which we know enough about hazard and exposure so that EPA should move to risk management without having to first conduct additional risk assessment?

Senator Thomas R. Carper

1. In your recommendations for TSCA Reform, I do not believe you mentioned any role for your agency's Office of Research and Development, is that correct? Do you believe the agency –specifically the Office of Research and Development – should help bridge any data gaps that now exist for our toxic chemicals?

2. What is the agency doing now to bridge these gaps – how many resources are going toward toxic chemical research?

3. What percentage of funding for the Office of Research and Development is going toward the research of criteria pollutants as opposed to the research of air toxics?

4. In recent testimony in the House, I believe EPA's Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances Stephen Owens indicated that the EPA will be evaluating an initial set of chemicals and developing what were termed "action plans" for them. Can you provide further details about these "action plans?" Is the EPA planning on engaging stakeholders in that process? Can you also describe that for me?

5. In your statement, you say that the EPA should have a "clear authority to set priorities for conducting safety reviews." Can you please expand on what you mean by "clear authority" and how we would prioritize chemicals?

Senator Benjamin L. Cardin

1. Throughout our lives we are exposed to thousands of chemicals. They are in the air we breathe, the water we drink, and the products we touch and use. Many chemicals are fairly innocuous - particularly at low levels of exposure. However, there is so little we know about the chemical content and safety of the products we use that it is often difficult to know their effects on human health.

- Since the ultimate goal is to protect public safety, should chemical regulation standards be based on risks and effects on human health?

2. The human body does a miraculous job of keeping itself safe and healthy. From warding off infections from bacteria and viruses, to filtering out common air and water pollutants, to processing and disposing toxins we ingest deliberately. While the body is

able to process and dispose many of the harmful toxins that come in, some accumulate in our bodies and as our exposure increases the risks escalate as well.

- Would EPA support an approach to chemical regulation that places a priority on addressing those chemicals that pose the greatest risk to human health and have a tendency to accumulate over time?

3. The chemical industry has developed many fantastic products that have improved our lives. Plastics have revolutionized the way we live and chemicals used to purify water and treat disease have made us healthier. I understand that much of the research, development and commercial viability of these products would not be possible without allowing chemical producers to conduct their business with a relative degree of confidentiality and protection of intellectual property.

As law makers and protectors of the public's welfare, it is our responsibility to put the public's safety first. The public has the right to know when the chemicals in the products they use may pose a risk to their lives.

- Under TSCA, do producers of potentially dangerous chemicals found in some products have any responsibility to disclose the risks that these products may pose to consumers?

4. Individual pharmaceutical companies, automakers and food producers all develop, market and sell unique products within their sector. These companies reserve a certain right to protect trade secrets which is vital to the principle of keeping a competitive marketplace. Yet all of these industries are also subject to rigorous safety requirements that must be met before a product reaches consumers.

- To your knowledge, have product safety requirements and public disclosure of potential hazards violated companies' commercial rights to protect trade secrets?

Senator James M. Inhofe

1. Are there existing authorities under TSCA that you feel EPA is not using to the fullest extent? Are there others that are? Please thoroughly describe each.

2. We have heard you allege that TSCA hinders EPA's ability to collect relevant information on chemicals. But, EPA already has a plan in place to do just that for High Production Volume chemicals. Under the HPV Challenge Program, companies make health and environmental effects data publicly available on chemicals that are produced or imported in the greatest quantities. More than 2,200 HPV chemicals have been evaluated. Despite the success of the program, EPA has not finalized the last rule for HPV testing, even though it was due to complete it over a year ago. Can you explain to me the reasons for the delay in finalizing this last piece of the HPV testing program? Isn't this program a good example of what EPA can do to improve chemical reviews using existing authorities?

3. Witnesses testified that there are over 80,000 chemicals used and produced today. That statement is in direct contrast to previous EPA statements – which called that figure "misleading." What is the actual number of chemicals currently in commerce in the United States? How is this number different from previous EPA counts? In view of your principles for TSCA reform, how can EPA regulate chemicals if they cannot be consistent with the number of chemicals in commerce?

4. Reports indicate that there are approximately 200 chemicals for which testing has been obtained using section 4. But, EPA also has authority to require testing using 5(e) and has also successfully relied on voluntary efforts to obtain test data. How many new chemicals have been made subject to 5(e) orders which include testing, including triggered testing, among their requirements? For how many new chemicals has EPA relied on voluntary means (eg, so called "ban pending testing" approaches)? For how many existing chemicals has EPA relied on voluntary means to obtain test data (eg, under the HPV Challenge Program)?

5. In testimony before the House, EPA suggested that the ChAMP program was canceled "after a careful review." But, I am not convinced. Please give me a detailed description of what and who was involved in the review of ChAMP, and why the decision was made to end this widely supported program. Wasn't EPA making progress under ChAMP?

6. You suggest that TSCA does not include a mandatory review program for the safety of chemicals. However, EPA is currently evaluating an initial set of chemicals - based on available hazard, exposure, and use information - for potential regulatory action. So which is it? If EPA needs more authority to regulate, under what legal authority are you doing these initial reviews? How is ChAMP different than what EPA is now doing?

7. Do you believe an increase in animal testing will need to be done in order to obtain the type of data EPA that will need for prioritizing? If so, how much? How reliable is computer modeling in this area?

8. Unfortunately, the chemicals that you cite in your statement as "new potential threats" do not fall squarely within TSCA. For example, BPA in baby bottles, phthlates in medical devices, and lead in toys are each regulated under the new law CSPIA by the CSPC. Further, major exposures from dioxins in fish are not associated with TSCA uses. Given the inapplicability of the examples you cited, could you instead please identify specific problems that fall to TSCA's authorities that you believe compel legislative action?

9. Both Canada and the EU are requiring the generation of new data on chemicals, and such data should be utilized to avoid unnecessary and duplicative U.S. testing requirements in a revised TSCA. What mechanisms will EPA utilize to share chemical information with international governments?

10. Embedded in both EPA and industry TSCA reform principles is the concept of "safety determination." In EPA's view, who would issue the "safety determination," and what would the "safety determination" mean in practice? What are the benefits and challenges of using this process for chemical management review at EPA? Please provide details on how you envision this process working.

11. EPA has recently announced a comprehensive approach to enhance the Agency's current chemicals management program within the limits of existing authorities. As posted on the Agency's website, EPA intends to utilize the full array of regulatory tools under TSCA to address risks, including authority to label, restrict, or ban chemicals under Section 6 of TSCA. Yet, in the past, EPA has stated that it is unable to effectively utilize Section 6 as a tool to limit or ban chemicals. Can you explain, then, how EPA intends to regulate these chemicals in its revamped existing chemicals strategy?

Senator David Vitter

1. What options/opportunities do you see being available to EPA to help promote innovation without deteriorating confidence in government management of toxic chemicals while protecting domestic jobs?

2. Do you see as beneficial EPA establishing a system to quickly identify and review "priority" chemicals based upon both hazard characteristics and exposures, including exposures to children?

3. Why are OMB and NASA pushing for NAS review of EPA's Trichloroethylene assessment? Do you believe this shows a lack of confidence in EPA's IRIS assessment?

AL-14-001-2516

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
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Minority (202) 225–3641

July 15, 2014

The Honorable Jim Jones
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Assistant Administrator Jones:

Thank you for appearing before the Subcommittee on Environment and the Economy on Tuesday, April 29, 2014, to testify at the hearing on the discussion draft entitled the "Chemicals in Commerce Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Tuesday, July 29, 2014. Your responses should be mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed to Nick.Abraham@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member, Subcommittee on Environment and the Economy

Attachment

The Honorable Henry A. Waxman

Despite testimony over the past seven hearings on TSCA that the new chemicals program under current law has largely been a success, the revised draft implements a number of substantial changes to this program. These include new exemptions for articles and byproducts, as well as a new analytical standard under which EPA must determine whether or not regulation "is warranted." The purpose and effects of these changes are not clear.

1. Do other laws implemented by EPA require determinations of whether regulation "is warranted?" If so, has that standard been interpreted in the past as requiring a cost-benefit analysis? Has the "is warranted" standard posed any difficulties for implementation?

In your written testimony, you suggested that these new changes would have an adverse effect on the new chemicals program, weakening current law.

For instance, you state that EPA's risk management authorities for new chemicals under the discussion draft would be weaker than those in current TSCA.

2. Please explain this concern in detail.

The draft also weakens current law with respect to EPA's ability to respond where there is insufficient information. Under current law, when EPA receives a PMN for a new chemical and finds that there is insufficient information to evaluate the chemical's risks, EPA has a number of options, including requiring the development and submission of test data pursuant to section 4. The draft would curtail some of these authorities.

3. What steps would EPA have to take under the revised draft to obtain the information needed for new chemical reviews?

4. Would these steps take additional time and/or resources, compared to the current process, and if so, what effects could that have?

There has been consensus among a broad group of stakeholders that chemicals should be held to a risk-based safety standard under a reformed TSCA. This has been part of EPA's principles for TSCA reform since 2009. You testified that the standard in the discussion draft is a "risk/cost balancing" standard similar to what exists under current law and that it "does not align with the approach delineated in [EPA's] principles."

At the same time, you testified that EPA needs to have the flexibility to consider costs in risk management.

5. In EPA's view, should costs of risk management options play a role in determining whether or not a chemical meets a risk-based standard?

6. In EPA's view, should the Agency have discretion to consider costs in choosing among available risk-management options that would be adequate to bring a chemical into compliance with a risk-based standard?

The Honorable John D. Dingell

1. In 1976 I submitted report language in regard to weaknesses that exist in the current Toxic Substances Controlled Act. I stated it was essential for the protection of public health and the environment that EPA

have a firm mandate for a comprehensive approach to protection from hazards due to chemical substances. And, that such a success could only be achieved through legislative directives and adequate funding support. Mr. Jones, you state in your testimony that, in order to be successful, EPA must have the resources it needs to protect the American people from exposure to harmful chemicals.

a. Under CICA, does EPA have the appropriate resources to quickly and efficiently implement the various framework, process, criteria, and guidance provisions which must be in place prior to EPA beginning action on specific chemicals?

b. Under CICA, once EPA is able to take action on a specific chemical, does EPA have the resources needed to quickly and efficiently determine prioritizations, assessments, determinations, and risk managements?

2. EPA has over 84,000 chemicals listed on its TSCA inventory, and little over 200 have been acted on in 37 years. EPA has identified an initial work plan of chemicals for assessment which includes 83 substances, in addition to identifying several hundred chemicals on the Safer Chemicals Ingredients List.

a. Under current TSCA, does EPA have the appropriate resources to complete more than 20 risk assessments per year on existing chemicals? Please answer yes or no.

b. What kind of resources would EPA need in order to perform 10 to 20 more additional risk assessments per year?

3. As you know, I have the privilege to live in the Great Lakes region, home to 20 percent of the world's fresh water supply as well as tremendous hunting and fishing areas. Many of my constituents have voiced concerns that CICA does not ensure adequate public health and safety standards needed for high-risk toxic chemical contamination found in this region.

a. Would EPA be better able to regulate new and existing chemicals if they were granted the authority to set priorities for conducting safety reviews based on relevant risk and exposure conditions?

b. If both chemical manufacturers and EPA had the ability to asses and act on priority chemicals like those potentially found in the Great Lakes, would EPA be better able to regulate those chemicals in a timely manner?

AL-061-8177

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

JOE BARTON, TEXAS
RANKING MEMBER

ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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Majority (202) 225–2927
Minority (202) 225–3641

October 25, 2010

Mr. Steve Owens
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Mr. Owens:

Thank you for appearing before the Subcommittee on Commerce, Trade, and Consumer Protection on July 29, 2010, at the hearing entitled "Toxic Chemicals Safety Act of 2010."

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions.

Please provide your responses by November 8, 2010, to Earley Green, Chief Clerk, via e-mail to Earley.Green@mail.house.gov. Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,

Henry A. Waxman
Chairman

Attachment

The Honorable Henry A. Waxman and the Honorable Bobby L. Rush

1. At the hearing, questions were raised with respect to the toxicity of antimicrobial chemicals, such as those used in hand cleaners, and the appropriate regulatory treatment of such substances in a variety of applications. Based on your experience in assessing and authorizing the use of some antimicrobial chemicals for use in pesticides, do you have any comments on these issues raised with respect to antimicrobials and the feasibility of regulating their use while protecting public health and the environment?

2. The safety standard proposed in the Toxic Chemicals Safety Act – a "reasonable certainty of no harm" to vulnerable populations, taking into account aggregate exposure – draws from the safety standard that is contained in the Food Quality Protection Act of 1996 and that has been implemented by EPA for more than a decade. Some have suggested that this standard is inherently unworkable, or that it will require a level of proof that will be impossible to meet.

   a. Please describe your experiences with implementation of the Food Quality Protection Act as they relate to the workability of the "reasonable certainty of no harm" standard.

   b. Does EPA believe that under current law, EPA receives adequate health and safety data to conduct a robust safety assessment of all new chemicals? Please explain.

3. During the hearing, there seemed to be some disagreement about whether individual companies would be required to conduct aggregate exposure assessments under H.R. 5820, or whether that requirement would apply only to EPA.

   a. Please provide the Committee with your views on whether H.R. 5820 would require individual manufacturers and processors to conduct aggregate exposure assessments on chemicals.

   b. Please also provide your views on how the burden of proof provisions of the bill relate to the question of whether or not individual companies will be required to perform aggregate exposure.

4. One issue that arose during the hearing was the question of how reforming TSCA might affect efforts to reduce the incidence of cancer in the U.S. A number of chemicals have been identified by the National Toxicology Program (NTP) and/or the International Agency for Research on Cancer (IARC) as known human carcinogens. For many of these chemicals, exposure is widespread within the United States.

   a. What authority should EPA have under a revised TSCA to address the threats posed by known human carcinogens where there is evidence of widespread exposure? How should TSCA be modified to better address the risks posed by these chemicals?

b. Do you think the changes to TSCA proposed in H.R. 5280 are sufficient, go too far, or do not go far enough? Please explain.

The Honorable Joe Barton

1. How many FTEs would your office have to hire to assure meaningful implementation of H.R. 5820?

2. Section 4 of the legislation would give EPA the power to require more testing based upon a "substantial risk" of injury to health or the environment. Does the term "substantial risk" have a well understood meaning under TSCA?

3. You stated in your testimony that there are 84,000 chemicals listed on the TSCA Inventory.

    a. Is it realistic to believe EPA could review all of the tens of thousands of data sets industry would be required to submit to EPA under H.R. 5820, assuming industry could compile and submit all of the data required under the bill? If yes, how long would it take EPA to complete all of the chemical reviews required under this bill?

    b. Can you estimate the costs of compiling minimum data sets for a chemical substance or mixture? If yes, what would be the range of costs to do the testing and what is the basis for your estimate?

    c. Are there currently enough laboratories in the U.S. to perform the testing that would be required under this bill for each of the 84,000 chemicals on the TSCA inventory? On what basis can you assure Congress that there exists enough laboratory capacity to perform this testing as well as perform R&D on new chemicals and on green products?

4. Has EPA considered the economic effects of the chemical action plans and other regulatory actions it currently plans to take under existing TSCA?

5. H.R. 5820 would impose significant new requirements on new chemicals and new uses of chemicals. Notably, the bill would impose a one-year deadline on the approval of pre-manufacturing notices (PMNs), a substantial increase over the 90-day period now provided under TSCA.

    a. What impact would the provision likely have on companies that have very short product cycles, such as those in electronics or semi-conductor industries?

    b. How does the United States rank, compared to other regions of the world, in the number of new chemical notices filed each year?

6. H.R. 5820 would require EPA to apply the safety standard to ensure that "public welfare is protected." How does EPA define "public welfare"?

7. H.R. 5820 would require EPA to develop guidance on the use of science in its safety determinations. The agency would be directed to rely on the recommendations of the National Academy of Sciences report on "Science and Decisions."

a. The NAS report includes a recommendation that assessments be based on cumulative exposures. Does EPA agree that the level of knowledge required to conduct a cumulative assessment, even for a group of chemicals that share a common mechanism of toxicity, is orders of magnitude over and above that required to conduct an aggregate assessment, and that it is not practical for the vast majority of chemical substances, mixtures and uses?

b. In the roughly 14 years since enactment of the Food Quality Protection Act, EPA has only been able to conduct a cumulative risk assessment for four groups of pesticide common ingredients, and those were for pesticides with common routes of exposure. Does EPA agree that cumulative assessments would be far more difficult for thousands of chemical substances, mixtures, and articles covered under H.R. 5820 -- and the very different exposure patterns they create across all their many uses -- than it has been in the pesticides context?

8. Under H.R. 5820, importers of chemical substances, mixtures, and articles would be subject to the full range of EPA's authority under section 4 (data generation), section 5 (new chemical and new use requirements), section 6 (safety determinations) and section 8 (declarations and reporting). By its terms, this provision would apply to any manufactured article imported into the United States that contains a chemical substance or mixture.

   a. How many articles are currently regulated in some fashion under TSCA?

   b. How many articles could be regulated in some fashion under this provision in H.R. 5820?

   c. Has EPA performed any assessment of the additional resources that would be required to implement the import provisions of H.R. 5820?

9. You testified that chemical manufacturers should support the costs of agency implementation of TSCA, including the cost of reviewing information provided by manufacturers to EPA. How should they do so? Does EPA advocate new taxes or user fees as proposed in H.R. 5820? If so, please explain.

10. You testified EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with the flexibility to consider a range of factors, including economic costs, social benefits, and equity concerns. Under H.R. 5820, how would EPA consider economic costs, social benefits, and equity concerns? How did EPA consider these factors in crafting its chemical action plans?

11. EPA is proficient at listing chemicals under TSCA Section 5(b)(4), claiming these chemical substances present or may present an "unreasonable risk of injury." What is the criterion the agency uses to decide what constitutes an "unreasonable risk of injury" for purposes of this listing?

12. H.R. 5820 would establish minimum pre-manufacture data sets for new chemicals, and new uses of chemicals subject to a safety determination.

    a. How much is a minimum data set for new chemicals or new uses of chemicals likely to cost the manufacturer or processor?

    b. How likely is it that a manufacturer or processor of a new chemical product will have all the data required for a minimum data set prior to filing a pre-manufacture notice?

    c. Isn't it true that a premanufacturing notice is typically filed well before there is complete knowledge of whether a market exists?

    d. Isn't it true that nearly all new chemicals or new uses enter the market at low volumes not likely to pose significant risk concerns?

    e. H.R. 5820 eliminates the possibility of public notice and comment on proposed safety determinations and the risk management actions taken because of those determinations. Should EPA provide notice and an opportunity for public comment on proposed safety determinations and risk management actions?

13. Under TSCA, the amount of PCBs in electrical equipment has steadily declined due to a partnership between EPA and electric utilities on a long-standing and protective regulatory program to manage and reduce the use of PCBs in electrical equipment. Under H.R. 5820, should the United States ratify the Stockholm Convention, Congress would cede its legislative authority to an international standard for PCBs and other chemical substances; this will potentially pre-empt established, and working, U.S. standards with international recommendations contained in the Stockholm Convention. The practical effect of this change in legal requirements could mean that the electric utility industry would have to identify and remove from service all PCB-containing equipment, even equipment that is functioning properly and well.

    a. In your review of H.R. 5820, have you analyzed this aspect of the bill and do you think that is a wise use of resources? If so, why do you think so?

14. A majority of the Members of the Energy and Commerce Committee oppose regulation of coal combustion byproducts (CCBs) or residuals (CCRs) as a special listed waste under RCRA's hazardous waste rules. One of the primary reasons for opposing the regulation of CCRs under the hazardous waste regulations is because of the likely adverse effect it might have on the beneficial use of CCRs.

    a. Under H.R. 5820, would EPA consider CCBs or CCRs to be a chemical substance or mixture governed by sections 4, 5, 6, and 8 of this legislation?
    b. Has EPA evaluated what effect this bill would have on the beneficial use of CCRs? If not, wouldn't that be appropriate given the level of congressional support for these beneficial uses?

15. EPA is in the process of developing a number of different rules to increase the level of control on power plant emissions. Whatever the outcome, this will result in the need to implement new measures and employ innovative technologies to control emissions. The existing and new chemicals that are necessary for such emissions control requirements are regulated under TSCA and would be affected by the proposed changes to TSCA being made by H.R. 5820.

    a. Has EPA looked at this issue, either in the context of its air emissions rulemaking or internal analyses of H.R. 5820?

    b. Has EPA asked the Department of Energy to provide to the Agency its analysis of the potential effects of H.R. 5820 on future domestic electricity production and costs?

    c. Are you aware of any chemical substance or mixture, necessary to meet new and increasingly demanding emissions control requirements, which is commercially available and that today would be able to comply with all the requirements in sections 4, 5, 6, and 8 of H.R. 5820?

AL-10-000-5191

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

April 7, 2010

Steve Owens
Assistant Administrator
Office of Prevention, Pesticides and Toxic Substances
Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 7101M
Washington, DC 20460

Dear Mr. Owens:

Thank you for appearing before the Committee on Environment and Public Works on February 4, 2010. We appreciate your testimony, and we know that your input will prove valuable as we continue our work on this important topic.

Enclosed are questions that have been submitted by Senators Sanders, Klobuchar, Inhofe and Vitter for the hearing record. Please submit your answers to these questions by COB April 21, 2010 to the attention of Heather Majors, Senate Committee on Environment and Public Works, 410 Dirksen Senate Office Building, Washington, D.C. 20510. In addition, please provide the Committee with a copy of your answers via electronic mail to Heather_Majors@epw.senate.gov. To facilitate the publication of the record, please reproduce the questions with your responses.

Again, thank you for your assistance. Please contact Grant Cope of the Majority Staff at (202) 224-8832, or Rebeckah Adcock of the Minority Staff at (202) 224-6176 with any questions you may have. We look forward to reviewing your answers.

Sincerely,

Barbara Boxer
Chairman

James M. Inhofe
Ranking Member

Environment and Public Works Committee Hearing
February 4, 2010
Follow-Up Questions for Written Submission

Questions for Owens

Questions from:

Senator Bernard Sanders

1. The Breast Cancer Fund recently pointed out that food additives are not covered by the Toxic Substances Control Act (TSCA) and BPA may be considered an indirect food additive. What tools does EPA have, independently or working with other agencies, to ban BPA? If current tools do not allow a ban of BPA, what additional authority or tools are needed, in your view?

Senator Amy Klobuchar

1. One naturally occurring toxin, Radon, can easily finds its way into people's homes and produce severe long term health problems. Aside from smoking, it's the leading cause of lung cancer in this country. From a public health perspective, are we doing enough to address the threat of radon?

2. The Government Accountability Office (GAO) has issued several reports on toxic substances policies in the last few years. Last year, GAO placed EPA's chemical management program on its "high risk" programs and found that chemical assessment poses a major management challenge. How is the EPA and how are other government agencies coordinating their risk assessments and health assessments?

3. How can inter-agency coordination be improved?

Senators James M. Inhofe and David Vitter

1. Last year, EPA unceremoniously scrapped the ChAMP program, allegedly "after a careful review." But, I am not convinced and, according to recent news reports, neither are many career program employees. Please give me a detailed description of what and who was involved in the review of ChAMP, and why the decision was made to end this widely supported program. Wasn't EPA making progress under ChAMP?

2. We continually hear that there are "over 80,000 chemicals used and produced today." That statement is in direct contrast to previous EPA statements – which called that figure "misleading." What is the actual number of chemicals currently in commerce in the United States? How is this number different from previous EPA counts?

3. You suggest that TSCA does not include a mandatory review program for the safety of chemicals. However, EPA is currently evaluating an initial set of chemicals - based on available hazard, exposure, and use information - for potential regulatory action. So

which is it? If EPA needs more authority to regulate, under what legal authority are you doing these initial reviews?

4. Embedded in both EPA and industry TSCA reform principles is the concept of "safety determination." In EPA's view, who would issue the "safety determination," and what would the "safety determination" mean in practice? What are the benefits and challenges of using this process for chemical management review at EPA? Please provide details on how you envision this process working.

5. Both Canada and the EU are requiring the generation of new data on chemicals, and such data should be utilized to avoid unnecessary and duplicative U.S. testing requirements in a revised TSCA. What mechanisms will EPA utilize to share chemical information with international governments?

6. What about IUR reporting, PMN submissions and PAIR rules? Don't they provide information on exposures?

7. Will placing more of a burden on industry really reduce the burden on EPA, which, I assume, would still have to review and make decisions on the information submitted by companies? If so, how?

AL13-000-7483

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

July 16, 2013

James Jones
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, DC 20460

Dear Mr. Jones:

On behalf of the Senate Committee on Environment and Public Works, we invite you to testify before the Committee at a hearing entitled, "Hearing on the Nominations of Kenneth Kopocis to be Assistant Administrator for the Office of Water of the U.S. Environmental Protection Agency (EPA), James Jones to be Assistant Administrator for the Office of Chemical Safety and Pollution Prevention of the EPA, and Avi Garbow to be General Counsel for the EPA." The hearing will be held on Tuesday, July 23, 2013, beginning at 10:00 AM in Room 406 of the Dirksen Senate Office Building. The purpose of this hearing is to consider the nominations of Kenneth Kopocis to be Assistant Administrator for the Office of Water of the EPA, James Jones to be Assistant Administrator for the Office of Chemical Safety and Pollution Prevention of the EPA, and Avi Garbow to be General Counsel for the EPA.

In order to maximize the opportunity to discuss this matter with you and the other witnesses, we ask that your oral testimony be limited to five minutes. Your written testimony can be comprehensive and will be included in the printed record of the hearing in its entirety, together with any other materials you would like to submit.

To comply with Committee rules, please provide 100 double-sided copies of your testimony at least 48 hours in advance of the hearing to the Committee at the following address: 410 Dirksen Senate Office Building, Washington, DC 20510-6175. To ensure timely delivery, the copies of testimony must be hand delivered to 410 Dirksen. Please do not send packages through FedEx, U.S. Mail, or overnight delivery services, because they will be subject to offsite security measures which will delay delivery. Please also email a copy of your testimony (in both MS Word and as a PDF file) to the attention of Mara Stark-Alcalá, Mara_Stark-Alcala@epw.senate.gov, at least 48 hours in advance.

If you plan to use or refer to any charts, graphs, diagrams, photos, maps, or other exhibits in your testimony, please deliver or send one identical copy of such material(s), as well as 100 reduced (8.5" x 11") copies to the Committee, to the attention of Mara Stark-Alcalá, Mara_Stark-Alcala@epw.senate.gov, to the above address at least 48 hours in advance of the hearing. Exhibits or other materials that are not provided to the Committee by this time cannot be used for the purpose of presenting testimony.

If you have any questions or comments, please feel free to contact Grant Cope of the Committee's Majority staff at 202-224-8832 or Bryan Zumwalt of the Committee's Minority staff at 202-224-6176.

Sincerely,

Barbara Boxer
Chairman

David Vitter
Ranking Member

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

July 16, 2013

Avi Garbow
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, DC 20460

Dear Mr. Garbow:

On behalf of the Senate Committee on Environment and Public Works, we invite you to testify before the Committee at a hearing entitled, "Hearing on the Nominations of Kenneth Kopocis to be Assistant Administrator for the Office of Water of the U.S. Environmental Protection Agency (EPA), James Jones to be Assistant Administrator for the Office of Chemical Safety and Pollution Prevention of the EPA, and Avi Garbow to be General Counsel for the EPA." The hearing will be held on Tuesday, July 23, 2013, beginning at 10:00 AM in Room 406 of the Dirksen Senate Office Building. The purpose of this hearing is to consider the nominations of Kenneth Kopocis to be Assistant Administrator for the Office of Water of the EPA, James Jones to be Assistant Administrator for the Office of Chemical Safety and Pollution Prevention of the EPA, and Avi Garbow to be General Counsel for the EPA.

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Sincerely,

Barbara Boxer
Chairman

David Vitter
Ranking Member

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

July 16, 2013

Kenneth Kopocis
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, DC 20460

Dear Mr. Kopocis:

On behalf of the Senate Committee on Environment and Public Works, we invite you to testify before the Committee at a hearing entitled, "Hearing on the Nominations of Kenneth Kopocis to be Assistant Administrator for the Office of Water of the U.S. Environmental Protection Agency (EPA), James Jones to be Assistant Administrator for the Office of Chemical Safety and Pollution Prevention of the EPA, and Avi Garbow to be General Counsel for the EPA." The hearing will be held on Tuesday, July 23, 2013, beginning at 10:00 AM in Room 406 of the Dirksen Senate Office Building. The purpose of this hearing is to consider the nominations of Kenneth Kopocis to be Assistant Administrator for the Office of Water of the EPA, James Jones to be Assistant Administrator for the Office of Chemical Safety and Pollution Prevention of the EPA, and Avi Garbow to be General Counsel for the EPA.

In order to maximize the opportunity to discuss this matter with you and the other witnesses, we ask that your oral testimony be limited to five minutes. Your written testimony can be comprehensive and will be included in the printed record of the hearing in its entirety, together with any other materials you would like to submit.

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If you have any questions or comments, please feel free to contact Grant Cope of the Committee's Majority staff at 202-224-8832 or Bryan Zumwalt of the Committee's Minority staff at 202-224-6176.

Sincerely,

Barbara Boxer
Chairman

David Vitter
Ranking Member

AL-11-000-7778

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 23 2011

THE ADMINISTRATOR

The Honorable Joseph Biden
President of the Senate
United States Senate
Washington, D.C. 20510

Dear Mr. President:

As part of the President's Fiscal Year 2012 Budget, the Administration indicated that it would submit draft legislation to Congress to collect certain fees under the Toxic Substances Control Act (TSCA), the Federal Food Drug and Cosmetic Act (FFDCA), and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Enclosed for your consideration are two proposed bills, with section by section summaries.

The effect of the draft bills on the deficit is:

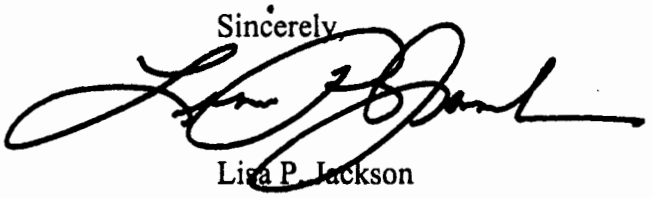
	Fiscal Years (dollars in millions)											
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Total
Net Deficit impact	0	-49	-81	-88	-95	-97	-101	-104	-107	-110	-114	-946

The Statutory Pay-As-You-Go Act of 2010 requires that the cumulative effects of revenue and direct spending legislation meet a pay-as-you-go (PAYGO) requirement. In total, such legislation should not increase the on-budget deficit; if it does, it would produce a sequestration if it is not fully offset by the end of the Congressional session. This proposal would reduce direct spending and is therefore in compliance with the Statutory PAYGO Act.

The Administration looks forward to working with the Congress to enact this legislation. The Office of Management and Budget advises that enactment of these proposals would be in accord with the program of the President.

Thank you for your consideration of these proposals. If you have any questions, please contact me or your staff may contact Sven-Erik Kaiser at (202) 566-2753.

Sincerely,



Lisa P. Jackson

Enclosures

A BILL

To amend the Pesticide Registration Improvement Renewal Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug, and Cosmetic Act in relation to fees, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. AMENDMENT TO FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT TO AUTHORIZE COLLECTION OF CERTAIN FEES.

(a) Section 4 of the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C.136a-1) (the "Act") is amended -

(1) by striking subsection (i)(5)(A) and inserting in lieu thereof "IN GENERAL.—Subject to other provisions of this paragraph, each registrant of a pesticide shall pay an annual fee by January 15 of each year for each registration.";

(2) in subsection (i)(5)(C), by striking "$22,000,000 for each of fiscal years 2008 through 2012" and inserting in lieu thereof "$47,000,000 in fiscal year 2012, $49,000,000 in fiscal year 2013, $50,000,000 in fiscal year 2014, $52,000,000 in fiscal year 2015, $53,000,000 in fiscal year 2016, $55,000,000 in fiscal year 2017, $57,000,000 in fiscal year 2018, $59,000,000 in fiscal year 2019, $61,000,000 in fiscal year 2020, $63,000,000 in fiscal year 2021,and each year thereafter.";

(3) by striking subsection (i)(5)(D) in its entirety and relettering the remaining sections;

(4) in subsection (i)(5)(E)(i)(I), by striking "for each of fiscal years 2008 through 2012";

(5) in subsection (i)(5)(E)(i)(II), by striking "for each of fiscal years 2008 through 2012"; and

(6) in subsection (k)(2)(A), by striking the first two sentences and inserting in lieu thereof the following:

"All moneys derived from fees collected by the Administrator under subsection (i) shall be deposited in the Fund. Of the amounts collected in fiscal year 2012, $22,000,000 is hereby appropriated, and shall be available until expended. Amounts collected in excess of $22,000,000 in fiscal year 2012 are authorized to be appropriated, to remain available until expended. Amounts collected in any subsequent fiscal year, are authorized to be appropriated, to remain available until expended."

(b) Section 33 of the Act (7 U.S.C. 136w-8) is amended -

(1) by striking subsection (b)(6) and inserting the following -

"(6) Fee adjustment.

"(A) The Administrator shall increase the service fees payable for applications under paragraph (3) of section 33(b) submitted during fiscal year 2012 and each fiscal year thereafter by the amount calculated by the Administrator to result in the collection, during each such fiscal year, of an additional $17,000,000 more than what was collected in 2011,

"(B) The fees required by section 33(b) shall be automatically adjusted annually by the same percentage as the adjustment in rates of pay for the General Schedule pay system, either as provided in section 5303 of title 5,

United States Code, or in accordance with another provision of law which supersedes that section.

"(C) The Administrator shall publish in the Federal Register the revised registration service fee schedule.";

(2) by striking subsection (c)(4); and renumbering the remaining paragraph;

(3) by striking subsection (d) (2) and (4) and by renumbering the remaining paragraphs;

(4) by striking subsection (j) and relettering the remaining subsections; and

(5) by striking subsection (m).

SECTION 2. AMENDMENT TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.

Section 408(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(m)), is amended by striking paragraphs (1) through (3) and replacing them with the following -

"(1) Amount. The Administrator shall develop and publish in the Federal Register a schedule of fees within 90 days of the date of enactment of this Act that will, in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. This schedule shall include separate fee requirements, calculated to cover the Administrator's costs of responding to the particular activity, for-

(A) the acceptance for filing of a petition submitted under subsection (d); and

(B) the certification and filing in court of a transcript of the proceedings and the record under subsection (h).

In setting the tolerance fee schedule, the Administrator shall consult with the Secretary of Agriculture to consider impacts to minor uses. The Administrator shall not perform any function under this section for which a fee is required pursuant to this paragraph unless that fee has been paid in full.

"(2) Annual Fee Adjustment. The fees required by this section shall be automatically adjusted annually by the same percentage as the adjustment in rates of pay for the General Schedule pay system, either as provided in section 5303 of title 5, United States Code, or in accordance with another provision of law which supersedes that section. When these automatic adjustments are made, the Administrator shall publish notice of the adjusted fee schedule in the Federal Register as a final rule to become effective 30 days or more after publication.

"(3) Pesticide Tolerance User Fee Account. There is established in the Treasury of the United States a Pesticide Tolerance User Fee Account. Amounts authorized to be collected pursuant to subsection (m)(I) shall be deposited in this account. Amounts in the Pesticide Tolerance User Fee Account are authorized to be appropriated, to remain available until expended."

Section-by-Section Summary

Section 1 (a)(1) amends Section 4(i)(5)(C) of FIFRA to increase collections of the Maintenance fee from $22 million to $47 million in 2012, $49,000,000 in fiscal year 2013, $50,000,000 in fiscal year 2014, $52,000,000 in fiscal year 2015, $53,000,000 in fiscal year 2016, $55,000,000 in fiscal year 2017, $57,000,000 in fiscal year 2018, $59,000,000 in fiscal year 2019, $61,000,000 in fiscal year 2020, $63,000,000 in fiscal year 2021,and each year thereafter. This section would improve per product fee equity and provide increased flexibility to EPA in establishing fee schedules by removing the firm-based ceilings for fees, except in the case of small businesses. This section also authorizes the Administrator to deposit fees into the Reregistration and Expedited Processing Fund and appropriates $22 million of those deposits in fiscal year 2012. Amounts collected above that level, and amounts collected in subsequent years, are authorized to be appropriated in subsequent Acts.

Section 1(b) amends section 33(b)(6) of FIFRA to increase Registration Service fee collections in fiscal year 2012 by $17 million above fiscal year 2011 collections, increasing collections each year thereafter with an automatic annual adjustment. This section also removes the minimum appropriation required in order for EPA to maintain fee collection authority.

Section 2 amends section 408(m) of FFDCA by directing that tolerance fees be deposited into a new Pesticide Tolerance User Fee Account rather than in the Registration and Expedited Processing Fund and makes those fees available for use subject to appropriations. Section 2 also provides for an automatic annual adjustment of these fees and directs the Administrator to publish notification of the adjusted fees in the Federal Register.

A BILL

To amend the Toxic Substances Control Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. AMENDMENT TO TOXIC SUBSTANCES CONTROL ACT.

Section 26(b) of the Toxic Substances Control Act (15 U.S.C. 2625) is amended in paragraph (1) -

(1) by striking "may" in the first sentence and inserting in lieu thereof "shall";

(2) by striking "any fee in excess of $2,500 or"; and

(3) by inserting in the third sentence "small business concerns and" after "account".

Section-by-Section Summary

This bill amends section 26(b) of the Toxic Substances Control Act (15 U.S.C. 2625) to eliminate the statutory cap on the amount of the fee that can be collected by the Environmental Protection Agency (EPA) for data submitted under section 4 or 5 of the Act. The cap will remain in place for small businesses as defined by this section.

Paragraph (1) is further amended to maintain the current requirement that in setting the fee, the Administrator shall take into account small business concerns as well as the applicant's ability to pay.

This bill does not revoke EPA's existing regulations regarding fees (40 C.F.R. part 700, subpart C).

AL-10-001-6183

RICHARD SHELBY
ALABAMA

RANKING MEMBER—COMMITTEE ON BANKING, HOUSING, & URBAN AFFAIRS
COMMITTEE ON APPROPRIATIONS
RANKING MEMBER—SUBCOMMITTEE ON COMMERCE, JUSTICE, SCIENCE, & RELATED AGENCIES
SPECIAL COMMITTEE ON AGING

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WASHINGTON, DC 20510–0103
(202) 224-5744

United States Senate

WASHINGTON, DC 20510–0103

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321 FEDERAL BUILDING
BIRMINGHAM, AL 35203
(205) 731–1384

○ HUNTSVILLE INTERNATIONAL AIRPORT
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BOX 20127
HUNTSVILLE, AL 35824
(256) 772–0460

○ 113 SAINT JOSEPH STREET
445 U.S. COURTHOUSE
MOBILE, AL 36602
(251) 694–4164

○ 15 LEE STREET
FMJ FEDERAL BLDG., SUITE 208
MONTGOMERY, AL 36104
(334) 223–7303

○ 1118 GREENSBORO AVENUE, #240
TUSCALOOSA, AL 35401
(205) 759–5047

September 13, 2010

Director
Congressional and Intergovernmental Relations
Environmental Protection Agency
1200 Pennsylvania Ave. N.W. Rm 3426 ARN
Washington, D.C. 20460-0001

Dear Director:

Enclosed, please find a copy of correspondence I received from Charles E. Morgan.

Please review the enclosed and address the concerns raised. I have notified my constituent to expect a timely reply directly from you.

Sincerely,

Richard Shelby

Richard Shelby

RCS/amy
Enclosure

RICHARD SHELBY
ALABAMA

RANKING MEMBER—COMMITTEE ON BANKING, HOUSING, & URBAN AFFAIRS
COMMITTEE ON APPROPRIATIONS
RANKING MEMBER—SUBCOMMITTEE ON COMMERCE, JUSTICE, SCIENCE, & RELATED AGENCIES
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  (251) 694–4164
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  FMJ FEDERAL BLDG., SUITE 208
  MONTGOMERY, AL 36104
  (334) 223–7303
- 1118 GREENSBORO AVENUE, #240
  TUSCALOOSA, AL 35401
  (205) 759–5047

September 13, 2010

Mr. Charles E. Morgan
Sr. Executive Vice President & General Counsel
Phifer Incorporated
Post Office Box 1700
Tuscaloosa, Alabama 35403-1700

COPY

Dear Charles:

Thank you for taking the time to contact me regarding proposed EPA regulations.

I have contacted the EPA on your behalf and have asked them to respond to your concerns. You should expect a reply to your concerns directly from the agency in a timely manner. Please do not hesitate to contact me about this or other matters in the future.

Sincerely,

Richard

Richard Shelby

RCS/amy

COPY

140503
809426

PHIFER
INCORPORATED

■ CHARLES E. MORGAN
Senior Executive Vice President and General Counsel

August 11, 2010

Hon. Richard C. Shelby
SH-110 Hart Senate Office Building
2nd Street & Constitution Ave.
Washington, DC 20510-0103

Dear Senator Shelby:

I am writing because I am concerned about the Environmental Protection Agency ([redacted])'s intended inclusion of DINP and DIDP on a proposed TSCA Section 5(b)(4) list of "Chemicals of Concern." DINP and DIDP have been extensively reviewed from a scientific and regulatory perspective, including evaluations the National Toxicology Program, the U.S. Consumer Product Safety Commission and the European Chemicals Bureau. In addition, in Europe, intensive and comprehensive government risk assessments of DINP and DIDP have concluding they are safe for all intended uses. Data from the Centers for Disease Control and Prevention confirms that human exposures to these substances are very low.

EPA's intended action will put businesses and local economies in jeopardy by causing marketplace uncertainty, which leads to unwarranted substitution of safe products with alternatives that in all likelihood are less studied, thus increasing the risk to consumers and the environment, the very things EPA is trying to protect.

Phifer Incorporated expends considerable resources developing the best process and using the ideal components for the manufacture of our product line. We also very carefully consider the safety of the chemicals and the design of all materials that go into Phifer products because producing safe products is a top priority. We have chosen DINP/DIDP based on these principles.

With this proposed EPA action, Phifer is now facing the prospect of having manufactured a product with a chemical that is being considered for listing, which is contrary to the numerous government assessments. We also face the prospect of demand for reformulation, which will again require considerable resources to develop and test alternatives that well may be more expensive, less available and not suitable for our performance needs. Consequently, there will be an increased risk of not being able to manufacture and produce the much-depended on products and/or higher product costs, increased liabilities, job loss, and business closure.

For these reasons, Phifer asks that you advocate with EPA to not proceed with a proposal to list DINP and DIDP under TSCA 5(b)(4) unless and until it has convened a Small Business Advocacy Review Panel and has carefully weighed the potential costs to business and health against any potential benefits given by listing these useful, economical, well-tested and well-reviewed chemicals.

P. O. Box 1700 • Tuscaloosa, Alabama 35403-1700 USA
Phone 205-750-4757 • FAX 205-750-3022 • charles.morgan@phifer.com

Sincerely yours,

PHIFER INCORPORATED

Charles Morgan

Charles Morgan

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV - 4 2010

OFFICE OF THE
ADMINISTRATOR

The Honorable Richard Shelby
United States Senate
Washington, DC 20510-0103

Dear Senator Shelby:

Thank you for your letter of September 13, 2010, to the U.S. Environmental Protection Agency (EPA) forwarding the concerns of your constituent, Mr. Charles E. Morgan, regarding EPA's pending action on diisononyl phthalate (DINP) and diisodecyl phthalate (DIDP). Please find enclosed EPA's response to your constituent's concerns.

Again, thank you for your letter and if you have any questions, please feel free to contact me at 202-564-5200 or your staff may contact Mr. Sven-Erik Kaiser in EPA's Office of Congressional and Intergovernmental Relations at (202) 566-2753.

Sincerely,

Joyce K. Frank
Principal Deputy Associate Administrator

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 22 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Charles E. Morgan
Senior Executive Vice President
and General Counsel
Phifer Inc.
P.O. Box 1700
Tuscaloosa, AL 35403-1700

Dear Mr. Morgan:

Thank you for your letter of August 11, 2010, to Senator Richard Shelby, regarding diisononyl phthalate (DINP) and diisodecyl phthalate (DIDP). Senator Shelby has asked the U.S. Environmental Protection Agency (EPA) to respond directly to you.

As you may know, in parallel with our support for strengthening U.S. chemical management laws, EPA is pursuing a comprehensive approach to enhance the Agency's current chemicals management program under the Toxic Substances Control Act (TSCA) and other authorities. One aspect of this approach is the development of Chemical Action Plans to focus the Agency's risk management efforts on chemicals of concern. EPA released a Phthalate Action Plan on December 30, 2009, addressing eight phthalates, including DINP and DIDP.

In 2008, the National Research Council of the National Academies of Science included DINP, as well as a number of other phthalates, in their recommendation of chemicals that should be considered for cumulative risk assessment, because human exposure is widespread and occurs to multiple phthalates at any one time. In addition, as part of the Consumer Product Safety Improvement Act of 2008, Congress included both DINP and DIDP in an interim ban on use in certain children's products, pending an evaluation of the cumulative effects of phthalates to be conducted by the Consumer Product Safety Commission (CPSC). Hence, there is documented concern about the potential for certain phthalates, including DINP and DIDP, to cause effects as the result of concurrent exposures and efforts to conduct cumulative assessments are currently underway.

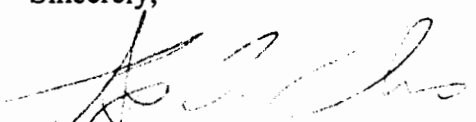
One action identified in the phthalate plan is to initiate rulemaking to add these eight phthalates to the Concern List under TSCA Section 5(b)(4). Section 5(b)(4) of TSCA authorizes the Administrator to compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.

Your letter requested that EPA convene a Small Business Advocacy Review Panel (SBAR) for this action. Based on the Agency's Regulatory Flexibility Analysis (RFA) for the proposed rule under TSCA section 5(b)(4), EPA has determined that the proposed rule as currently drafted is not expected to have a significant economic impact on a substantial number of small entities potentially regulated by the rule. EPA is not, therefore, required to convene an SBAR Panel under the RFA for this proposed rule.

The TSCA Chemicals of Concern List is to be compiled and kept current through rulemaking proceedings, including public notice and the opportunity to comment. That notice will provide an opportunity for public comments on this proposed action. EPA would welcome your comments on the pending proposal during the public comment period, including your concerns about the adequacy of the scientific findings and business impacts. We will give the comments thoughtful consideration as we work on the proposed Section 5(b)(4) list.

I hope this information has been helpful to you. If you have any further questions, please feel free to contact Ms. Maria Doa, Director of the National Program Chemicals Division, at (202) 566-0718.

Sincerely,



Stephen A. Owens
Assistant Administrator

cc: Hon. Richard Shelby

AL-10-000-2664

FRANK R. WOLF
10TH DISTRICT, VIRGINIA

COMMITTEE ON APPROPRIATIONS

SUBCOMMITTEES:

RANKING MEMBER—COMMERCE-JUSTICE-SCIENCE

TRANSPORTATION-HUD

CO-CHAIR—TOM LANTOS
HUMAN RIGHTS COMMISSION

Congress of the United States
House of Representatives

February 3, 2010

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WINCHESTER, VA 22601
(540) 667-0990
(800) 850-3463 (IN STATE)

wolf.house.gov

Ms. Joyce Frank
Acting Associate Administrator For
Environmental Protection Agency
1200 Pennsylvania Ave N.W.
Room 3426 ARN
Washington DC 20460

Dear Ms. Frank:

I received the enclosed letter from my constituent, Mr. Engle, of Round Hill, Virginia, sharing with me his concern that the 1976 Toxic Substances Control Act may allow companies to keep secret harmful chemicals in their products.

I would appreciate any comments that you may have on this matter for me to share with Mr. Maio. I ask that you please fax your response to me at 202-225-0437, attention: Andrew Bender.

Thank you for your assistance in helping me to serve my constituents.

Best wishes.

Sincerely,

Frank R. Wolf
Member of Congress

FRW:ab
enclosure

Exp-U and

JAN 12 2010

January 4, 2010

Representative Frank R. Wolf
241 Cannon Office Building
Washington DC 20615-4610

Dear Congressman Wolf:

I read in this morning's Washington Post, an article: "Law allows companies to hide risks of chemicals" *By Lyndsey Layton*. The article says that the 1976 Toxic Substances Control Act, in order to protect trade secrets, allows companies to cloak chemicals in their products, even if those chemicals are harmful to people or to the environment.

A horrible example given in the article was where a nurse, after treating an oil worker became seriously ill with a failing liver and lungs filling with fluid. The company, Weatherford International, would not provide the doctors with a list of the ingredients to help them save her life.

It is not rare that the law cloaks potentially harmful chemicals. In March 2009, according to the Post, more than half the 65 substantial risk reports involved secret chemicals. Considering the apparent frequency that harmful chemicals are cloaked, it is not inconceivable that some of the mysterious ailments affecting our children (ADHD, for example) are the result of those cloaked ingredients.

I don't believe everything I read in newspapers so let me ask you this – is the Washington Post article substantially accurate?

If the Post is accurate to the extent that the public is exposed to secret harmful ingredients will you do something, such as try to revise the law to allow only benign ingredients to be cloaked?

I would appreciate a response to these two questions.

Sincerely,

Exp-U

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 15 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

The Honorable Frank R. Wolf
U.S. House of Representatives
Washington, DC 20515-4610

Dear Congressman Wolf:

Thank you for your letter dated February 3, 2010, to the U.S. Environmental Protection Agency (EPA) on behalf of your constituent, Mr. Kyle, concerning confidentiality under the Toxic Substances Control Act (TSCA).

EPA looked into the matter referenced in the Washington Post article regarding Weatherford International and it appears that the issue does not relate to information that was submitted under TSCA. However, claiming confidentiality under TSCA or other environmental statutes would not prevent a company from making its own information public or providing ingredient information to physicians during a patient's care.

TSCA, this country's chemical management law, provides broad protection of proprietary confidential information about chemicals in commerce. TSCA was enacted in 1976, and has not been reauthorized since. EPA Administrator Lisa Jackson has made enhancing EPA's chemical management program a priority which includes support for legislative reform of TSCA as well as utilizing our current authorities to the fullest extent possible. In September 2009, EPA announced a set of Administration principles to help inform discussions on modernizing and strengthening the current law in order to increase confidence that chemicals used in commerce are safe and do not endanger the public health and welfare of consumers, workers, and especially sensitive sub-populations such as children, or the environment. One of the principles calls for stricter requirements for a manufacturer's claim of Confidential Business Information (CBI) and for manufacturers to substantiate their claims of confidentiality. The Administration's Principles for TSCA reform may be found at http://www.epa.gov/oppt/existingchemicals/pubs/principles.html.

EPA, however, is not waiting for legislative reform to further the goal to increase transparency and the public's access to information about chemicals. EPA is moving forward on identifying mechanisms to increase the amount of useful data available to the public on chemicals in commerce. In July 2009, EPA announced that it would move 530 chemical substances from the confidential to the public portion of the TSCA Inventory List. In January 2010, EPA announced efforts to identify and reject claims of confidentiality in notices of substantial risk (TSCA Sec. 8(e)), when the claims are unwarranted.

On March 15, 2010, EPA began providing web access, free of charge, to the TSCA Chemical Substance Inventory. This inventory contains a consolidated list of thousands of industrial chemicals maintained by the Agency. EPA is also making this information available on Data.gov, a website developed by the Obama Administration to provide public access to important government information. In addition, on March 30, 2010 at a national meeting of chemical manufacturers, I issued a challenge to industry. First, I invited them to carefully review new TSCA filings to limit confidentiality claims to only that information allowed to be secret under the law and to the material that truly needs to be secret. Second, I called on industry to start reviewing older filings with materials claimed as CBI, to reconsider the need for the continued confidentiality, and where possible, release the information to the public. I will soon be making additional information on this request publicly available.

In the coming months, EPA will announce and pursue additional activities to increase transparency and make more information available to the public. This includes adding TSCA facility information, and the list of chemicals manufactured at those facilities, to the Facility Registry System (FRS). FRS is an integrated data base that provides the public with easier access to EPA's environmental information and better tools for cross-media environmental analysis. The addition of TSCA facility and chemical databases to FRS will provide the public with information on the facilities in their communities that manufacture and use industrial chemicals.

Again, thank you for your letter and I hope the information provided is helpful to you and your constituent. If you have additional questions, please contact me or your staff may contact Christina Moody in EPA's Office of Congressional and Intergovernmental Relations at (202) 564-0260.

Sincerely,

Stephen A. Owens
Assistant Administrator

AL-11-000-0953

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

January 10, 2011

The Honorable Richard Lugar
United States Senate
306 Hart Senate Office Building
Washington, DC 20510
ATTN: Ms. Darlee McCollum

Dear Senator Lugar:

Thank you for your letter of December 9, 2010, forwarding correspondence from Ms. [redacted] regarding reform of the Toxic Substances Control Act (TSCA).

TSCA provides the U.S. Environmental Protection Agency (EPA) with the authority to require reporting, record-keeping and testing requirements, restrictions relating to chemical substances and/or mixtures, and to address the production, importation, use, and disposal of specific chemicals. Because the EPA, and not the U.S. Consumer Product Safety Commission (CPSC), administers TSCA, we have referred your inquiry to the EPA for consideration.

I hope this information is helpful to you. Should you have any questions, please feel free to contact me by telephone at (301) 504-7660 or by e-mail at cday@cpsc.gov.

Very truly yours,

Christopher R. Day
Director
Office of Congressional Relations

cc: David McIntosh
Associate Administrator for Congressional
and Intergovernmental Relations
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Room 3426 ARN
Washington, DC 20460

RICHARD G. LUGAR
INDIANA

306 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
202-224-4814
http://lugar.senate.gov

COMMITTEES:
FOREIGN RELATIONS, RANKING MEMBER
AGRICULTURE, NUTRITION, AND FORESTRY

United States Senate

WASHINGTON, DC 20510-1401

December 9, 2010

Mr. Christopher Day
Director of Congressional Relations
U.S. Consumer Product Safety Commission
4330 E West Hwy
Bethesda, Maryland 20814

Dear Mr. Day:

Because of the desire of this office to be responsive to all inquiries and communications, your consideration of the attached is requested.

Your findings and views, in duplicate form, along with the return of the enclosure, will be greatly appreciated. Please direct your reply to the attention of Darlee McCollum of my Washington office.

Thank you for your thoughtful attention.

Sincerely,

Richard G. Lugar
United States Senator

RGL/cgd
Enclosure

~~Nov~~ 8, 2010

Senator Richard Lugar
Hart Senate Office Building, Room 306
Constitution Avenue and 2nd Street, NE
Washington, DC 20510-1401

01 NOV 24 P 12:00

Dear Senator Lugar,

As consumers, many of us will soon buy toys for our kids, grandkids, nieces and nephews as the holiday season nears. How can we buy toys without harming those we so dearly love? Would you knowingly distribute poison to the young???? That is what Toys R Us is doing.

In 2008, Toys R Us promised to reduce PVC plastic, phthalates and lead in children's and infant's toys. But the fact of the matter is that Toys R Us has not kept its promise, it has failed to label toxics in its toys and it has failed to get PVC, the poison plastic, out of the toys.

Independent product testing has confirmed that Toys R Us is selling brand new toys made with PVC. Chemicals released in PVC's lifecycle have been linked to chronic diseases in children, impaired child development and birth defects, cancer, disruption of the endocrine system, reproductive impairment and immune system suppression.

Toys R Us, as the largest specialized toy retailer in America, with more than 800 stores nationwide, has the economic power to eliminate toxics from the toy supply chain entirely. Because Toys R Us has refused to keep its promise, we demand that Congress hold hearings on the threat toxic materials present to our children.

PVC in toys and in toy packaging is an example of the need to reform federal law to protect consumers. I urge you to support legislation to reform America's outdated chemical policies that are failing to protect families from toxic chemicals and materials currently on the market. The federal law regulating industrial chemicals, the Toxic Substances Control Act (TSCA), is 30 years old, outdated, and simply does not sufficiently work to protect people and the environment.

Thanks in advance for your leadership on this important issue.

Sincerely,

Gary, IN 46403-1205

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 11 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

The Honorable Richard G. Lugar
United States Senate
Washington, DC 20510-1401

Dear Senator Lugar:

I am writing in response to your December 9, 2010, letter to the U.S. Consumer Product Safety Commission (CPSC) forwarding the concerns of your constituent, Ms. Eng-Co regarding the presence of toxic chemicals and materials, notably Polyvinyl chloride (PVC), in children's toys and her interest in reform of the Toxic Substances Control Act (TSCA). CPSC referred your letter to the U.S. Environmental Protection Agency (EPA) as the agency responsible for TSCA, to respond directly to your letter.

As you may be aware, EPA's Administrator Lisa P. Jackson strongly supports modernizing and strengthening U.S. chemical management so that EPA has clear authority to take appropriate risk management actions that protect public health and the environment. On September 29, 2009, Administrator Jackson announced a plan to enhance EPA's chemical management program as well as a set of Administration principles on TSCA reform to guide efforts to modernize and strengthen U.S. chemical management. As outlined in the principles, EPA should have clear authority to take appropriate risk management actions to protect the health of sensitive subpopulations, such as children.

As an example of EPA's commitment to reforming TSCA and protecting children's health, Administrator Jackson testified, on October 26, 2010, at a U.S. Senate Environment and Public Works Subcommittee on Superfund, Toxics and Environmental Health field hearing titled, "Toxic Chemicals and Children's Environmental Health." Administrator Jackson outlined the limitations of the current TSCA and discussed the special risks faced by children exposed to chemicals.

In parallel with our support for strengthening U.S. chemical management laws, EPA is using current authorities under existing TSCA to the greatest extent possible. This comprehensive approach includes the development of chemical action plans on a select number of chemicals and increasing the public's access to chemical information that is provided to the Agency. These action plans outline the Agency's concerns with the chemicals and identify the steps EPA is considering to address those concerns. Among the chemicals addressed by the action plans are eight phthalates, which are often used as plasticizers in materials such as PVC. The phthalates action plan indicated that EPA is considering action to address issues relating to the manufacturing, processing, distribution in commerce, and/or use of phthalates, including a rulemaking under TSCA that would list chemicals of concern.

Again, thank you for your letter and I hope the information provided is helpful to you and your constituent. If you have any additional questions or concerns, please contact me or your staff may contact Mr. Sven-Erik Kaiser in EPA's Office of Congressional and Intergovernmental Relations at (202) 566-2753.

Sincerely,

Stephen A. Owens
Assistant Administrator

AL-14-000-0576

Congressman John A. Boehner
U.S. House of Representatives
1-800-582-1001

1011 Longworth H.O.B.
Washington D.C. 20515
(202) 225-6205

7969 Cincinnati-Dayton Road
Suite B
West Chester, Ohio 45069
(513) 779-5400

12 South Plum Street
Troy, Ohio 45373
(937) 339-1524

12 South Plum Street

Troy, Ohio 45373

To: EPA Liaison

From: ☒ **Angie Harrah**
○ **Frank DeBrosse**

Fax: 202 501 1519 **Pages:**

Phone: **Date:** Oct. 28, 2013

Re: **CC:**

☒ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **FYI**

• **Comments:** Coast Guard Cutter Storis - confirmed reports of encapsulated PCB's aboard. Ship is being dismantled + towed out of the U.S. on 10/29. Constituent would like to know if this would fall under the Toxic Substances Control Act of 1976 - Dismantling, scrapping + towing (exporting)

If there is a problem with this fax, please call 1-937-339-1524

JOHN A. BOEHNER
SPEAKER
OHIO
H-232 U.S. CAPITOL BUILDING
WASHINGTON, D.C. 20515
(202) 225-0600

Congress of the United States
House of Representatives

WASHINGTON OFFICE:
1011 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-3508
(202) 225-5205
DISTRICT OFFICES:
7969 CINCINNATI-DAYTON ROAD, SUITE B
WEST CHESTER, OH 45069
(513) 779-5400
12 SOUTH PLUM STREET, 2ND FLOOR
TROY, OH 45373
(937) 339-1524
DISTRICT TOLL FREE NUMBER
1-800-582-1001

October 28, 2013

Congressional Inquiries
Congressional Liaison
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Room 3426 ARN
Washington, DC 20460-0003

Dear Congressional Liaison:

The enclosed correspondence, regarding whether the Coast Guard Cutter, Storis, having toxic substances aboard,would fall under the Toxic Substance Control Act of 1976, as it is being dismantled, scrapped and exported to Mexico on 10/29/2013, was sent to me by Thomas Wagner.

I would greatly appreciate your providing my Troy office with any appropriate information so that I can reply to my constituent.

If I can provide additional information, please do not hesitate to call me.

Sincerely,

John A. Boehner

JAB/ah

PRIVACY ACT RELEASE FORM

PLEASE PRINT CLEARLY

(Mr./Mrs./Ms. **Full Name:** Exp-6 **Nick Name:**

Address of Residence: Exp-6

City/State/Zip: Oxford Ohio 45056 **County** Butler

Phone #: Hon Exp-6 **Work (__)** **Other (__)**

Email Address: Exp-6

Please send completed forms to: **Congressman John Boehner**

Residents of Butler and Preble Counties:
7969 Cincinnati-Dayton Road
West Chester, Ohio 45069

Residents of Clark, Darke, Mercer, and Miami Counties:
12 South Plum Street
Troy, Ohio 45373

Due to the provisions of the Privacy Act of 1974 (Title 5, Section 552A of the United States Code) permission in writing is required before making an inquiry on your behalf. Completing and signing this form authorizes Rep. John Boehner and his staff to make inquiries to the appropriate officials on your behalf and to release information to him or his staff.

To begin your inquiry, provide all pertinent information:

Federal Agency Involved:_____

Social Security Number:_____ **Date Of Birth:**_____

Military ID#:_____ **Veteran's Claim #:**_____

Military Branch, Rank & Unit:_____

Alien #: A_____ **CIS/DOS Receipt #:**_____

Immigration -- Petitioner's Name:_____

Beneficiary's Name:_____

Other Numbers Identifying your claim:_____

Please briefly describe your situation and the action or result or the information desired. Use the back of this sheet, or attach a separate page, if necessary. Be sure to provide any necessary documentation.

_____

_____

_____

_____

SIGNATURE Exp-6 **DATE:**_____

U.S. Department of Transportation
United States Coast Guard

Memorandum

Subject: HAZMAT SURVEY OF CGC STORIS

Date: 15 NOV 2000
5100

From: Robert McMenamin, CG YARD

Reply to Attn. of: sm-110
R. McMenamin
410-636-3772

To: Commandant, G-CFM-3

1. The Coast Guard YARD was requested to conduct a Hazmat Survey on the CGC STORIS in Ketchikan AL. POC was LT. K. Smyth (EO). The survey was conducted on 8/10/00. All compartments that were accessible were surveyed. The results of the survey showed that the vessel does contain Polychlorinated Biphenyl's materials.

2. In addition, the survey showed no asbestos containing material on the vessel but an asbestos removal was underway during the survey.

NAD – No Asbestos Detected

Sample #	Location	Material Tested	Result
A-5	Passageway, 02-59-2, Port BKHD Insulation	Cork	NAD
A-6	Boiler Flat, Port Pre-Heater, COV Insulation	White fibrous material	NAD
A-7	Outside Repair 3, OVHD, 2" Pipe Hanger	Gasket, White cloth	NAD
A-8	Emergency Generator Room, Starboard BKHD, behind switch 1-161-1	Cork	NAD

3. Lead base paint (LBP) was found on the exterior and interior surfaces of the vessel. Results greater than 1.0 mg/cm^2 is considered lead based paint.

Sample#	Results	Location	Outer Paint Layer
1886	0.0	Bridge, Mid BKHD	Beige
1887	0.2	Bridge, Fire Extinguisher, 02-85-1	Red
1888	0.0	Bridge, Aft, Portside, BKHD	White
1889	0.0	Bridge, Fog Signal Timer	Grey
1890	0.0	Bridge, Mid BKHD, Starboard, Electric Box	Blue
1891	8.3	Bridge wing, Starboard, under Gyro Repeater	Dark Grey
1892	0.0	Bridge wing, Starboard, forward BKHD	White

1893	0.0	02 Deck, outside, Starboard under ladder to 03 deck	White
1894	0.0	02 Deck, Aft ladder	Black
1895	0.0	Bridge wing, portside under Gyro Repeater	Dark Grey
1896	0.0	Main Mast	SPAR
1897	0.0	03 Deck, portside antenna, HF Transmitter	Blue
1898	0.0	03 Deck, portside antenna, HF Receiver	Red
1899	0.0	Radio Rm., Starboard steel plate	White
1900	0.0	Fantail, FO vent, center	Yellow
1901	0.9	Fantail, port antenna	Red
1902	0.0	Fantail, Starboard capstan	SPAR
1903	0.0	Starboard Deck, FO vent	Yellow
1904	2.6	Paint Locker, Aft BKHD, Starboard side	White
1905	VOID		
1906	VOID		
1907	0.0	Paint Locker, Deck	Dark Grey
1908	4.3	Windlass Room, Aft BKHD	White
1909	6.5	Windlass Room, Deck	Dark Grey
1910	3.7	WTD to Lamp Locker	Green
1911	4.3	WTD to Bos'n Locker	Red
1912	10.0	Buoy Deck, Forward BKHD	White
1913	0.0	Buoy Deck, Deck	Dark Grey
1914	0.1	Buoy Deck, Safety lines around Main Hold Hatch	Yellow
1915	0.0	MPA Stateroom, door	Brown
1916	16.0	Refrigeration Machinery Space, 3-84-02-E, Aft BKHD	White
1917	0.0	Crews Berthing, 2-84-0-L, column	White
1918	7.5	Crews Berthing, Vent Cover, 2-110-2	White
1919	0.0	Crews Berthing, 2-63-02-L, Aft BKHD	Yellow
1920	0.0	Crews Berthing, 2-63-02-L, Portside Hull, Insulation Primer	Olive Green
1921	VOID		
1922	2.9	Repair 2, Starboard hull	Yellow, Zinc Chromate
1923	0.0	Engine Room, CME, LO Filter	Grey
1924	3.7	Engine Room, Port Hull	Dark Red
1925	0.0	Main Motor Room, Main Motor	Grey
1926	0.0	Main Motor Room, Frame for Main Motor	Red

Subj: HAZMAT SURVEY OF CGC STORIS

5100
15 NOV 2000

4. The following areas (listed by sample number) were tested for PCBs. All results above of 50 ng/g (ppm) is considered PCB containing/contaminated for regulatory purposes.

ND – Non Detected

Sample#	Results	Location	Material	Picture#
1768	ND	Bridge, Forward BKHD, Deck Mat	Black Rubber	1
1769	ND	Bridge, Forward BKHD, Deck Mat	Blue Rubber	1
1770	ND	Incinerator Room, Aft BKHD, Cable Hanger	Black Rubber	2
1771	ND	Radio Room, Floor Mat	Blue Rubber	3
1772	ND	CO's Head, Pipe Insulation	Black Foam	4
1773	ND	Passageway 01-95, Deck Mat	Black Rubber	5
1774	ND	Boiler Flat, Starboard OVHD, 3/4" Fuel Line, Pipe Hanger	Red Rubber	6
1775	ND	Buoy Deck, Sewage Connection, Portside, Flange Gasket	Black Rubber	7
1776	ND	Female Head, OVHD, Vent Gasket	Black Rubber	8
1777	ND	Recreation Room, Seat Cushion	Brown Vinyl	9
1778	ND	Recreation Room, Seat Cushion	Blue/Green Foam	9
1779	ND	Recreation Room, OVHD, 2" Fire Main, Pipe Insulation	Black Foam	10
1780	ND	Messdeck, under DC Plates, Pipe Insulation	Black Foam	11
1781	ND	Messdeck, Seat Cushion	Yellow & Green Foam	12
1782	ND	Messdeck, Seat Cushions	Blue Vinyl	12
1783	ND	CPO Head, Urinal Drain Line	Black Foam	13
1784	ND	CPO Head, CW Line to Toilet	Black Foam	14
1785	ND	CPO Head, CW Line over Sink, Pipe Hanger	Paper Gasket	15
1786	ND	PO1 Head, HW Line over Sink	Black Foam	16
1787	3	Ships Office, OVHD, 1" Line	Black Foam	17
1788	ND	Ships Office, OVHD, 2" Line, Pipe Insulation	Black Foam	18
1789	ND	Emergency Generator Room, Day Tank, Hatch Gasket	Rubber/Cork	19
1790	ND	Crews Berthing 2-84-0-L, Portside, Aft, Pipe Insulation	Black Foam	20
1791	ND	Crews Berthing 2-84-0-L, Portside, unpainted Pipe Insulation	Black Foam	21
1792	18	Refrigeration Machinery Space 3-84-02-E,	Grey Foam	22

		Portside, Compressor Filters		
1793	9	Reefer Flats, Non-skid	Non-Skid, Adheaive	23
1794	ND	Crews Berthing 2-63-01-L, Seat Cushions	Dark Brown Foam	24
1795	ND	Crews Berthing 2-63-01-L, Seat Cushions	Red Vinyl	24
1796	ND	Crews Head 2-63-02-L, Water lines to Deep Sink	Black Foam	25
1797	140	Repair 2, Starboard, Pipe Insulation	Black Foam	26
1798	ND	Repair 2, Carpet Mat	Felt (not Chromelock)	27
1799	ND	DC Shop, Portside, 2" Pipe Hanger	Red Rubber	28
1800	ND	Engine Room, Starboard, Sewage Lines near FR 136	Black Foam	29
1801	ND	Engine Room, Control Booth vent under Blower Switches, Insulation	Black Foam	30
1802	81	Auxiliary Shop, OVHD, 2" Sewage Line, Pipe Insulation	Black Foam	31
1803	ND	Main Motor Room, FW Manifold, Pipe Insulation	Black Foam	32
1804	ND	Main Motor Room, Fire Pump#3, Pipe Insulation	Black Foam	33
1805	ND	Generator Room #3, Deck Mat	Grey Rubber	34
1806	ND	Aft Steering, Forward BKHD, Cable Hanger	Black Rubber	35

5. I trust this information will be sufficient for your purposes, but if you have any questions concerning this survey, please contact me.

Robert D McMenamin

ROBERT D MCMENAMIN

Copy Commandant, G-SEN
Chief, Planning and Marketing, CG YARD
EO, CGC STORIS

John Nowakowski <lastpatrol@sbcglobal.com>
To: Sarah Pace <srpace@fuse.net>, "space " <space@fuse.net>, Thmanagre@gmail.com
Fwd: Fwd: Fwd: CGC STORIS - Illegally exported with PCBs

October 28, 2013 9:20 AM

6 Attachments, 2.8 MB

----- Forwarded Message -----
From: John Nowakowski <lastpatrol@sbcglobal.com>
To: Mark <Ryan.Mack@mail.house.gov>, Matthew Kaplan <matthew.kaplan@mail.house.gov>, Nadia Facey <Nadia.Facey@gmail.com>
Cc: Jon A. Ottman <jon.ottman@gmail.com>
Sent: Mon, 28 Oct 2013 06:48:10 -0400 (EDT)
Subject: Fwd: Fwd: CGC STORIS - Illegally exported with PCBs

Good Morning Everyone

The Last Patrol needs the assistance of the Senate and Congressional members from Ohio in regards to the ex-USCGC Storis
Senator Begich's office has also been contacted

Please find attached documentation and correspondence regarding the high likelihood that CGC STORIS was allowed on Friday to be towed from the Suisun Bay mothball fleet and cleared for export to Mexico for scrapping even though she contains encapsulated PCBs on board. This export would be in violation of the Toxic Substances Control Act of 1976 and importing the material into Mexico would violate the Basel Convention.

We have enlisted legal assistance in the matter and are attempting to stop the ship from leaving the country. You can see by the email tread below and the attached information the there is more than a good likely hood that GSA has not complied with the law. Once this has been verified we feel the sale contract of the ship should be rescinded and the ship returned to the mothball fleet. The people listed below can give all the back up documentation on this issue. Thank you for your help.

Best Regards,

John T. Nowakowski
419-351-2348 — Toledo Ohio

Contact info for the parties involved are:
Polly Parks - (804)410-2165 - Cell (703)339-6851 - email: polly.parks@bmgroup.com

attorney Denise Rapp, Cell- (202) 546-2533

Jon Ottman - (586)322-5817, Historical preservationist for the Last Patrol

-------- Original Message --------
Subject: Fwd: Fwd: Story on the Storis
Date: Sat, 26 Oct 2013 18:39:04 -0500 (CDT)
From: Storis Museum <storismuseum@verizon.net>
Reply-To: storismuseum@verizon.net
To: jon.ottman@gmail.com

FYI

Storis Museum
c/o Jim Loback, 10436 Teal Circle, Fountain Valley, CA 92708
Tel 714 968 8864, www.storismuseum.org
storismuseum@verizon.net

-------Original Message-------

From: Jay Barrett

Date: Oct 26, 2013 11:06:31 AM

Subject: Fwd: Story on the Storis

To: storismuseum@verizon.net

Howdy Storis Museum Folks,

I am trying to pass this on to Joe Gatchot, who I interviewed this week about the Storis. I got the e-mail below in response to it and wanted to pass it on. Let me know if there is a better e-mail to reach Joe.

Thanks,

Jay Barrett

KMXT Radio

Kodiak

Begin forwarded message:

> From: "Polly Parks" <Polly.Parks@emrgroup.com>

> Subject: Story on the Stark

> Date: October 25, 2013 at 2:56:35 PM AKDT

> To: "JAY [redacted]"

>

> Dear Jay,

>

> This story has legs. When I read your report in the Stars and Stripes this a.m., I fired off an email to Bill Noggle at EPA HQ as to whether the USCG, GSA, or the unidentified businessman had gotten a pcb export waiver as TSCA does not allow the export of PCBs above 50 ppm and I (and everyone in my company who works on scrapping ships for the US Navy, MARAD, and commercial vessels) knows these old ships have pcbs in them. I got in touch with the USCG and GSA representatives listed on the gsa auction site (links below) and asked if they or the businessman...I'll just attach everything it speaks for itself (and Mr. Beach stamped to call back the original report, but too late). This is background. You can do your own legwork, though they will know I gave you the PCB report. I have nothing back from EPA HQ or Region IX, so I have to unfortunately suspect they were getting ready to sign off based upon that PCB report that states explicitly that encapsulated PCBs were not removed. Both HQ and Region IX knows better. If that ship is going to be scrapped, it needs to be scrapped in the US.

>

> So the GSA auction info makes sense: in the explanation the inference is the vessel is functional, not obsolete; however, it is of note that CG insignia were removed, that infers they knew it would be scrapped outside the US because there is no need to do that in the US. No sense of hazmats or that pcbs might be involved. DSC Starks auction shows the two bids (probably one bidder with an automatic raise) and Starks bid history explains a little more of the bid process.

>

> Let me know if you have any questions. I work out of my house so the 804 number works, but I'm on eastern time.

>

> Polly Parks

> T: +1 (804)410-2184

> M: +1 (703)336-6891

> F: +1 (804)410-2185

> E: polly.parks@emrgroup.com <mailto:polly.parks@emrgroup.com>

> A: EMR USA - Southern, Washington DC Office, 218 Spotswood Lane, Colonial Beach, VA 22443

> usa.emrgroup.com <http://usa.emrgroup.com/>

>

>

>

Howdy Storis Museum Folks,

I am trying to pass this on to Joe Gaidhot, who I interviewed this week about the Storis. I got the e-mail below in response to it and wanted to pass it on. Let me know if there is a better e-mail to reach Joe.

Thanks,

Jay Barrett
KMXT Radio
Kodiak

Begin forwarded message:

> From: "Polly Parks" <Polly.Parks@emrgroup.com>
> Subject: Story on the Storis
> Date: October 25, 2013 at 2:39:35 PM AKDT
> To: <jay.barrett@kmxt.com>
>
> Dear Jay,
>
> This story has legs. When I read your report in the Stars and Stripes this a.m., I fired off an email to Bill Noggle at EPA HQ as to whether the USCG, GSA, or the unidentified businessman had gotten a pcb export waiver as TSCA does not allow the export of PCBs above 50 ppm and I (and everyone in my company who works on scrapping ships for the US Navy, MARAD, and commercial vessels), knows those old ships have pcbs in them. I got in touch with the USCG and GSA representatives listed on the gsa auction site (links below) and asked if they or the businessman...I'll just attach everything it speaks for itself (and Mr. Beach attempted to call back the hazmat report, but too late). This is background. You can do your own legwork, though they will know I gave you the PCB report. I have nothing back from EPA HQ or Region IX, so I have to unfortunately suspect they were getting ready to sign off based upon that PCB report that states explicitly that encapsulated PCBs were not removed. Both HQ and Region IX knows better. If that ship is going to be scrapped, it needs to be scrapped in the US.
>
> So the GSA auction info makes sense: is the explanation the tolerance is the vessel is functional, not obsolete; however, it is of note that CG insignia were removed, that letters they knew it would be scrapped outside the US because there is no need to do that in the US. No notice of hazmats or that pcbs might be involved. CGC Storis auction shows the two bids (probably one bidder with an automatic raise) and Storis bid history explains a little more of the bid process.
>
> Let me know if you have any questions. I work out of my house so the 804 number works, but I'm on eastern time.
>
> Polly Parks
>
> T: +1 (804)410-2168
>
> M: +1 (703)338-6861
>
> F: +1 (804)410-2169
>
> E: polly.parks@emrgroup.com <mailto:polly.parks@emrgroup.com>
>
> A: EMR USA - Southern, Washington DC Office, 216 Spotswood Lane, Colonial Beach, VA 22443
> usa.emrgroup.com
> <http://usa.emrgroup.com/>

Email with I...pdf (18 KB) Chris Rollin...I.pdf (24 KB) Storis arch r....pdf (2.3 MB) CGC Storis a....pdf (127 KB) CGC Storis a....pdf (120 KB) Storis bld h...y.pdf (83 KB)

NOTICE OF AWARD
(SALE OF GOVERNMENT OWNED PERSONAL PROPERTY)

CONTRACT NO: GS04P13EHB8671 DATE: 08/28/13

INVITATION NO: 41DSCC13425

PURCHASER:
BIDDER NO.: 232842
US METALS RECOVERY INC
7920 ALMAY ROAD
SAN DIEGO CA 92139
TEL: (619)823-5925
MARK@USMETALS.US

YOUR BID FOR THE FOLLOWING LISTED PROPERTY HAS BEEN ACCEPTED. PAYMENT OF BALANCE MUST BE RECEIVED ALONG WITH THE SECOND COPY OF THIS NOTICE AND PROPERTY MUST BE REMOVED BY DATES SPECIFIED IN THIS CONTRACT. UPON RECEIPT OF FULL PAYMENT, A RECEIPT OF PAYMENT WILL BE FORWARDED TO YOU TO PRESENT TO CUSTODIAN AS AUTHORITY TO REMOVE THE PROPERTY.

CONTRACTING OFFICER DATE

LOT NO.	DESCRIPTION	QUANTITY	UNIT
001	1942 UNITED STATES COAST GUARD STORIS (WMEC-38), MAKE/MANUFACTURER: TOLEDO SHIPBUILDING, MODEL: SUPPLY SHIP, DATE OF MANUFACTURE: APRIL 4, 1942, VESSEL NAME: USCGC STORIS, HULL NO: WMEC-38, SEAWORTHY: YES, VESSEL LENGTH: 230, ENGINE MISSING: NO, ENGINE HOURS: UNKNOWN, MARINE SURVEY: NO, THIS VESSEL IS A MEDIUM ENDURANCE CUTTER WHICH WAS USED FOR LAW ENFORCEMENT AND FISHERIES. CUTTER IS EQUIPPED WITH THREE END 8450G ENGINES CONNECTED TO THREE WESTINGHOUSE DC GENERATORS ... CONTINUED AS SHOWN ON INVITATION FOR BID	1	ET

PAYMENT INFORMATION: PAYMENT MUST BE MADE BY: 07/01/13

UNIT PRICE: 70100.00 PROPERTY MUST BE REMOVED BY: 07/12/13
TOTAL BID: 70100.00
DEPOSIT RECEIVED:
BALANCE DUE GOV'T: 70100.00

SELLING AGENCY:
GSA, FAS, 4DSCC
SALES OFFICE, STE. 130
77 FORSYTH STREET
ATLANTA
GA 30303
SALES MANAGER
TEL: (404)331-0040
FAX: (404)331-7584

DOT LOCATION:
U.S. MARITIME READY RESERVE FLEET
END OF LAKE HERMAN ROAD

BENICIA
CA 94510
JEFF BEACH
TEL: (202)372-3646
FAX: (202)372-3945

Warning: In order to view the most up-to-date information, please click the refresh button on your browser.

Item Information

CGC STORIS (WMEC-38) MEDIUM ENDURANCE CUTTER

Sale-Lot Number:	41QSCI13425001
City, State:	Benicia, CA
Current Bid:	70,100 USD (Reserve Not Met)
Bidders:	2
Close Time:	06/27 08:16 PM CT (Closed)
Time Remaining:	

Description | Bidding Details | Bid History

Note: When "Compatible" bidding occurs (two or more bids of the same amount are submitted), the "high bid" is determined by GSA Auctions system's evaluation, based on the time of submission and/or by proxy.

To enhance bidder privacy, and protect GSA Auctions users from fraudulent emails, GSA Auctions has changed how User IDs are displayed on the bid history page. Only you can view your User ID, all other members will see anonymous user IDs, such as Bidder*.

As of February 14, 2009 bidders will be assigned the actual bidder number for the sale/lot based on when they placed their bid, if you are the first bidder for this sale you will see Bidder#1, if you are the second bidder you will see Bidder#2.

Bidders in the Auction (Current top 10 bidders)

Bidder	Bid Amount	Date-Time
Bidder#2	(Reserve not met) 70,100 USD	06/27/2013 07:55:58 PM CT
Bidder#1	69,100 USD	06/27/2013 07:55:21 PM CT

Your Bids

Bid #	Bid Amount	Max Limit	Status	Date

No bids currently

(*) Possible Extension. See Bidding Rules.

Item Photos

Item Location

NOTE: Maps are not updated frequently and are likely to miss new addresses or show incorrect addresses. Please visit http://maps.google.com or http://www.mapquest.com for accurate property location and directions.

Go Green... Reuse is Recycling!

Carbon savings for this item are not available.

Select an Equivalency: Gallons of Gasoline Used

Click here for additional information.

Warning: In order to view the most up-to-date information, please click the refresh button on your browser.

Item Information

CGC STORIS (WMEC-38) MEDIUM ENDURANCE CUTTER

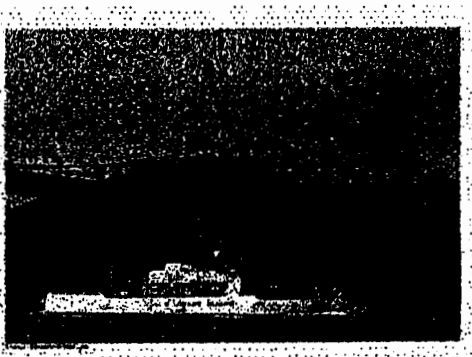
Sale-Lot Number:	41GSCI13425001
City, State:	Benicia, CA
Current Bid:	70,100 USD (Reserve Not Met)
Bidders:	2
Close Time:	08/27 08:15 PM CT (Closed)
Time Remaining:	

Description | Bidding Details | Bid History

BID DEPOSIT REQUIRED: $20,000.00

1942 UNITED STATES COAST GUARD STORIS (WMEC-38), MAKE/MANUFACTURER: TOLEDO SHIPBUILDING, MODEL: SUPPLY SHIP, DATE OF MANUFACTURER: APRIL 4, 1942, VESSEL NAME: USCGC STORIS, HULL NO: WMEC-38, SEAWORTHY: YES, VESSEL LENGTH: 230, ENGINE MISSING: NO, ENGINE HOURS: UNKNOWN, MARINE SURVEY: NO, THIS VESSEL IS A MEDIUM ENDURANCE CUTTER WHICH WAS USED FOR LAW ENFORCEMENT AND FISHERIES. CUTTER IS EQUIPPED WITH THREE EMD 645EG ENGINES CONNECTED TO THREE WESTINGHOUSE DC GENERATORS PROVIDING POWER TO ONE WESTINGHOUSE DC PROPULSION MOTOR (1800 HP)CUTTER REPOWERED IN 1988. PROPELLER IS 10 FEET-6 INCHES IN DIAMETER X 7 FEET-4 INCHES PITCH, 6 BLADE RH BRONZE. HULL IS RIVETED STEEL. FULL LOAD DISPLACEMENT IS 1710 LONG TONS. SHAFT BEARING FORWARD, ORION THRUST SHAFT BEARING AFT, THORDON. SHAFT SEALS FORE AND AFT: JOHN CRANE TYPE MX9, TANK CAPACITY DIESEL OIL 324 LONG TONS, FRESH WATER: 93 LONG TONS. COAST GUARD CREW SIZE: 10 OFFICERS AND 68 CREW MEMBERS WITH SEPARATE CREW QUARTERS FOR BOTH MEN AND WOMEN. LAST DRY DOCKING OF CUTTER WAS IN 2007 PRIOR TO ENTRY INTO THE READY RESERVE FLEET. HULL WAS CLEANED AND HULL RECOATED TO PREVENT SLUFFING OF HULL PAINT. THE TWO, 22 FOOT, MODEL H630 ZODIAC BOATS CURRENTLY ON BOARD THE CUTTER WILL CONVEY WITH THE CUTTER BOAT HIN: XDC63246C000 AND XDC63193E698. CUTTER ALSO EQUIPPED WITH A HYDRAULIC CARGO BOOM ON FORWARD PART OF THE CUTTER. CUTTER WAS ORIGINALLY DESIGNED TO BE A SUPPLY VESSEL FOR OPERATIONS IN GREENLAND (NORTH ATLANTIC, THE CUTTER HAS SOME DEGREE OF ICE BREAKING CAPABILITY. SHIP CIRCUMENAVIGATED NORTH AMERICA VIA NORTHWEST PASSAGE WITH CGC CUTTERS BRAMBLE AND SPAR IN 1957. VESSEL ADDED TO THE REGISTER OF HISTORICAL PLACES IN DECEMBER 2012. CUTTER HOMEPORTED IN ALASKA 1990 UNTIL 2007 WHEN IT WAS REMOVED FROM ACTIVE SERVICE AND MOVED TO THE RRF, SUISUN BAY, CA. THE CONDITON CODE OF "REPAIRABLE" DUE TO REMOVAL OF SHIP ELECTRONICS AND ABSENCE OF WORKING RADIO OR WORKING RADAR. NEXT OWNER/OPERATOR WILL HAVE TO PROVIDE A VALID CERTIFICATE OF FINANCIAL RESPONSIBILITY (COFR) BEFORE ACCEPTING CUSTODY OF THE CUTTER. NEXT OWNER/OPERATOR ALSO RESPONSIBLE FOR ANY REQUIREMENTS TO CLEAN HULL FOR COMPLIANCE WITH NON-INDIGENOUS SPECIES ACT BEFORE CUTTER DEPARTS SAN FRANCISCO BAY AREA. ON BOARD INSPECTIONS ARE HIGHLY ENCOURAGED AND CAN BE ARRANGED BY CONTACTING JEFF BEACH AT USCG HEADQUARTERS IN WASHINGTON, DC AT (202) 372-3646, OR EMAIL: JEFF.L.BEACH@USCG.MIL SHIP VISITS WILL A COUPLE OF DAYS ADVANCE NOTICE AND ARE SUBJECT TO ESCORT AVAILABILITY. THE PHOTO LISTED FOR THE CGC STORIS SHOWS CUTTER WITH FULL COAST GUARD MARKINGS AS THE SHIP TRAVELS UNDER THE GOLDEN GATE BRIDGE. ALL COAST GUARD MARKINGS HAVE BEEN REMOVED FROM THE SHIP AND IT NOW HAS AN ALL WHITE HULL. LAST DDX 2007.*****THIS ITEM REQUIRES A BID DEPOSIT OF $20,000. BID DEPOSITS MUST BE IN THE FORM OF A CASHIER-S CHECK OR

Item Photos



Item Location

NOTE: Maps are not updated frequently and are likely to miss new addresses or show incorrect addresses. Please visit http://maps.google.com or http://www.mapquest.com for accurate property location and directions.

Go Green... Reuse is Recycling!

Carbon savings for this item are not available.

Select an Equivalency: Gallons of Gasoline Used

Click here for additional information.

MONEY ORDER AND SHOULD BE MADE OUT TO G.S.A. AND MAILED TO: GSA, 4QSCA, 77 FORSYTH STREET, SUITE 100, ATTN: TONYA DILLARD, ATLANTA, GA 30303. PROSPECTIVE BIDDERS MUST PROVIDE THEIR GSAAUCTIONS LOGIN NAME, SALE AND LOT NUMBER, ADDRESS, TELEPHONE NUMBER, AND EMAIL ADDRESS. ONCE BID DEPOSIT HAS BEEN RECEIVED, BID RIGHTS WILL BE ASSIGNED*****ALL BID DEPOSITS WILL BE RETURNED WITHIN FIVE BUSINESS DAYS FROM THE CLOSING DATE OF THE SALE. ALL BIDDERS MUST BE REGISTERED*****ALL BID DEPOSITS MUST BE RECEIVED BY 12 NOON ON JUNE 28, 2013***** ALL BIDDERS MUST BE REGISTERED VIA GSAAUCTIONS.GOV WEBSITE*****CREDIT CARDS WILL NOT BE ACCEPTED FOR BID DEPOSITS***** REPAIRS MAY BE REQUIRED***** STARTING JUNE 20TH THRU JUNE 27TH, POTENTIAL BIDDER MAY CALL CAPTAIN PATRICK FLYNN AT 202-372-3552 TO OBTAIN INFORMATION OR SCHEDULE APPOINTMENTS***** Z700983127I.001A

THE CONDITION OF THE PROPERTY IS NOT WARRANTED.

Click here for pricing guides.

SPECIAL INSPECTION INFORMATION

POTENTIAL BIDDERS ARE URGED TO INSPECT THE VESSEL PRIOR TO

PLACING A BID. PROPERTY MUST BE PAID FOR NO LATER THAN

JULY 1, 2013.

Please contact the custodian for inspection dates and times and for removal arrangements.

PROPERTY REMOVAL: Due to security issues at property locations, successful bidders are required to contact the custodian prior to entering the facility to remove property, and at times, they are not permitted to use security phones. Therefore, successful bidders must communicate with the custodians in advance to make arrangements for removal and/or have a cell phone with them to contact them once they arrive at the secured location.

Successful bidders are cautioned that they will be responsible for loading, packing and removal of any and all property awarded to them from the exact place where the property is located, as indicated below.

Property Location and inquiries/questions regarding property inspection and/or removal:

U.S. Maritime Ready Reserve Fleet
End Of Lake Herman Road
Benicia, CA 94510

Contact: Jeff Beach
Phone: 202-372-3646
Fax: 202-372-3945
JEFF.L.BEACH@USCG.MIL

For inquiries/questions regarding payment, contact the following sales office:

GSA, FAS, 4QSCC
SALES OFFICE
77 FORSYTH STREET
ATLANTA , GA 30303

Phone: 404-331-0040
Fax: 404-331-7584

For inquiries/questions regarding contractual issues, contact the following sales contracting officer/property disposal specialist:

TONYA DILLARD
Phone: 404-331-0535
TONYA.DILLARD@GSA.GOV

(*) Possible Extension. See Bidding Rules.

Attachments can contain viruses that may harm your computer. Attachments may not display correctly.

Polly Parks

From: Polly Parks **Sent:** Fri 10/25/2013 11:05 AM
To: rollins.christopher@epa.gov
Cc: Chris Green; Jason Glascock; Tony Schultz; Tara Tomaslewicz
Subject: RE: Sale of 1942 USCG Storis for scrapping in Mexico
Attachments: Storis pcb report.pdf(2MB)

Dear Chris,

We are in receipt of the report. Page one, only those PCBs not encapsulated were certified as removed. Sorry Region IX got stuck with a hot federal potato again. Let us know if there is anything we can do to help.

Polly Parks
T: +1 (804)410-2168
M: +1 (703)338-6881
F: +1 (804)410-2168
E: polly.parks@emrgroup.com
A: EMR USA – Southern, Washington DC Office, 216 Spotswood Lane, Colonial Beach, VA 22443
usa.emrgroup.com

From: Polly Parks
Sent: Fri 10/25/2013 10:20 AM
To: rollins.christopher@epa.gov
Cc: Chris Green; Jason Glascock; Tony Schultz; Tara Tomaslewicz
Subject: FW: Sale of 1942 USCG Storis for scrapping in Mexico

Dear Chris,

I hope all is well. I understand you are looking into the UCG Storis which was sold to an unidentified businessman to be scrapped in Mexico. I've cc'd our environmental staff who can help you interpret whatever was sent over by the USCG to certify the 1942 build was indeed PCB-free. Our experience is that is impossible unless the vessel is dismantled; however, if the USCG has indeed developed a methodology that allows for the removal of all gaskets, etc. that are integrated into the construction without dismantlement, as long as it is cost-effective, we are, of course, eager to apply it commercially.

Best regards,

Polly Parks
T: +1 (804)410-2168
M: +1 (703)338-6881
F: +1 (804)410-2168
E: polly.parks@emrgroup.com
A: EMR USA – Southern, Washington DC Office, 216 Spotswood Lane, Colonial Beach, VA 22443
usa.emrgroup.com

From: Beach, Jeff L CIV [mailto:Jeff.L.Beach@uscg.mil]
Sent: Fri 10/25/2013 9:54 AM
To: Polly Parks; 'TONYA.DILLARD@gsa.gov'
Cc: 'william.noggle@EPA.GOV'
Subject: RE: Sale of 1942 USCG Storis for scrapping in Mexico

Ms Parks

Yesterday I forward to Mr. Chris Rollins of your San Francisco office a copy of the 2000 HAZMAT report on CGC

STORIS which did identify the presence of PCB material and a copy of the 2007 report that confirmed that the PCB material had been removed from the cutter and that the CGC STORIS was now PCB free.

Jeff Beach, CPPM
Manager of Retired CG Boats & Decommissioned Cutters
USCG Headquarters @ ST "E" Campus
(202) 372-3646

-----Original Message-----
From: prvs=0034ca9bc=Polly.Parks@emrgroup.com [mailto:prvs=0034ca9bc=Polly.Parks@emrgroup.com] On Behalf Of Polly Parks
Sent: Friday, October 25, 2013 9:36 AM
To: Beach, Jeff L CIV; TONYA.DILLARD@gsa.gov
Cc: william.noggle@EPA.GOV
Subject: Sale of 1942 USCG Storis for scrapping in Mexico

Dear Mr. Beach and Ms. Dillard,

I noticed the article in the Stars and Stripes this a.m. about the sale by the GSA for the USCG of the UGC Storis, which was nested at the SBRF; the article states the vessel is to be scrapped in Mexico. After visiting the GSA archive website and reviewing the solicitation, while it did mention the need to clean the vessel bottom to comply with the NISA, which means in drydock in the Bay Area, it did not mention that if bought for scrap the vessel contained hazardous material and that given the age of the vessel, it is almost certain to contain PCBs that would be subject to the TSCA PCB export ban. Did the USCG or GSA apply for a PCB export waiver prior to selling the vessel or was the successful bidder informed in writing, by your agencies that the vessel was subject to the PCB export ban? If this has not happened, the owner in all probability will be in violation of the TSCA export ban if the vessel is removed from the United States. Please let me, and Mr. William Noggle at the EPA, know what the status of the vessel, and who the successful bidder, is.

http://www.stripes.com/news/us/historic-coast-guard-cutter-headed-to-scrap-yard-1.248976#.Umpptxeby3w.email
http://gsaauctions.gov/gsaauctions/aucdsclnk?sl=41OSCI13425001#.UmpvJ2CC8JM.email

Sincerely,

Polly Parks
T: +1 (804)410-2168
M: +1 (703)338-6881
F: +1 (804)410-2168
E: polly.parks@emrgroup.com <mailto:polly.parks@emrgroup.com>
A: EMR USA - Southern, Washington DC Office, 216 Spotswood Lane, Colonial Beach, VA 22443
usa.emrgroup.com <http://usa.emrgroup.com/>

and for other lawful business purposes.

Warning: In order to view the most up-to-date information, please click the refresh button on your browser.

Item Information

CGC STORIS (WMEC-38) MEDIUM ENDURANCE CUTTER

Sale-Lot Number:	41QSCI13425001
City, State:	Berkeley, CA
Current Bid:	70,100 USD (Reserve Not Met)
Bidders:	2
Close Time:	06/27 08:15 PM CT (Closed)
Time Remaining:	

Description Bidding Details Bid History

Auction Description and Bidding Rules

This is an English auction. At the close of the auction, the user with the highest bid wins the auction, as long as that bid is at or above the auction's reserve price. The reserve price is the lowest price accepted for the item.

Once you submit a bid, you cannot cancel it, but you can replace it with a higher bid. When you submit a new higher bid, it replaces your previous one.

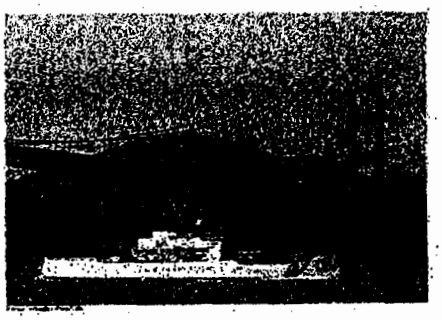
Click the Bid History link to see the bids you have submitted in this auction (My Bids).

Auction Properties

Current High Bid:	70,100 USD (Reserve Not Met)
Reserve Price:	true
Reserve Price Amount:	N/A
Bid Increment:	100 USD
Inactivity period:	20
Run length:	15
Inactivity period for reduction of Bid Increment:	2
Reduction of bid increment:	50
Reduction of bid increment limit:	100 USD
Start Time:	20130612 08:00 PM CT
Close Time:	06/27 08:15 PM CT
Closing Rules:	This auction will end in one of these ways: At the auction close time if no bids (proxy or flat) are placed within the inactivity period, or the auction is not subject to a inactivity period. After the inactivity period has passed without any bids (proxy or flat) being placed.
Status:	Closed

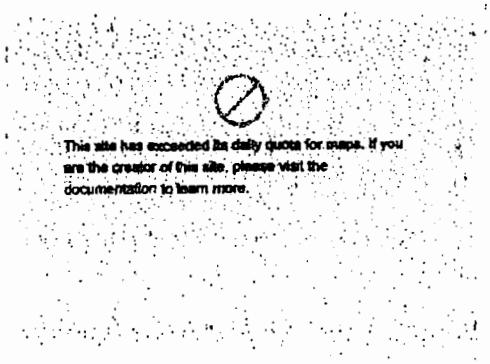
Note: "N/A" or a blank indicates that the value is not available for this auction.

Item Photos



Item Location

NOTE: Maps are not updated frequently and are likely to miss new addresses or show incorrect addresses. Please visit http://maps.google.com or http://www.mapquest.com for accurate property location and directions.



Go Green... Reuse is Recycling!

Carbon savings for this item are not available.

Select an Equivalency: Gallons of Gasoline Used

Click here for additional information.

How To Bid

Placing a Bid

GSA Auctions only accepts minimum and maximum bids. A maximum bid is the maximum amount you are willing to pay for an item. Maximum bids are also referred to as proxy bids. When you place your maximum bid, GSA Auctions will use as much of your bid as needed to make you the current winner of the auction or to meet the auction's reserve price. The minimum bid you can place is either the starting price of the auction, or the current high bid plus the bid increment.

GSA Auctions only accepts bids in whole dollar amounts. Bids in partial dollar amounts, $150.25 for example, will not be accepted by the GSA Auctions system.

Reserve Price

The reserve price is the minimum price that GSA Auctions is willing to accept for an item. If your maximum bid equals or exceeds the reserve price, your bid will be placed at the reserve price.

How Are The Bids Resolved in GSA Auctions? If a bidder places a bid with the same proxy bid amount as another bidder, the previous (first) bidder will have the current high bid since their bid was placed first. Both bids are recorded with the same amount, displaying the first bidder with the same amount as current high bid, until another bidder bids higher.

Competing Proxy Limits

When two proxy bids compete, the greater of the two proxy limits always wins. If the greater proxy limit exceeds the lesser proxy limit by the bid increment, then a bid equal to the lesser proxy limit plus the bid increment will be placed. If the greater proxy limit does not exceed the lesser proxy limit by the bid increment, then the greater proxy limit's maximum bid will be placed.

Increasing Your Maximum Bid

You can increase your maximum bid if you are currently the winner in an auction. To increase your maximum bid, enter an amount greater than your current maximum bid. Increasing your bid will not increase your current high bid.

Decreasing Your Maximum Bid

You can decrease your maximum bid if you are currently the winner in an auction. To decrease your maximum bid, enter an amount less than your current maximum bid. You cannot decrease your bid below the minimum bid price.

Maximum Bid / Proxy Bid

Your maximum bid or proxy bid, submits bids on your behalf. You specify the maximum price you are willing to pay. If you are outbid, the system submits a replacement bid at a higher price to keep you in the auction. It will bid as much as your maximum bid but no more.

Your maximum price is not shown to any other bidders.

If the system reaches your maximum bid limit, it stops bidding for you. Submit another bid if you want to continue bidding.

Winning & Trading

The highest bid at the close of the auction wins.

If your bid is lower than the reserve price, you will not win the auction.

Reduction of Bid Increment Notes

The reduction of bid increment happens when there is no bid activity within a specified time for an auction. The system will decrease the incremental bid amount by a percentage upto a limit based on template codes designed for this purpose. All auctions are not subject to the reduction of bid increment rule. Here's an example: A bid increment is set at $25.00 for an auction. A No-Bid-Period has been set for 2 days at a reduction rate of 10 percent and a reduction limit of $20.00. After 2 full days of inactivity for the auction, the bid increment will be reduced by 10 percent now making the current bid increment $22.00. 10 percent of $25.00 = $2.50 rounded to the nearest dollar $3.00. The reduction is repeated for multiple inactivity periods until the reduction limit is reached or auction closes.

(*) Possible Extension. See Bidding Rules.

Polly Parks

From: Polly Parks **Sent:** Fri 10/25/2013 11:24 AM
To: Beach, Jeff L CIV
Cc: 'TONYA.DILLARD@gsa.gov'; rollins.christopher@epa.gov; Noggle.William@epamail.epa.gov; Chris Green; Jason Glascock; Tony Schultz; Tara Tomaslewicz; Randy Boudreaux; Robert Berry
Subject: RE: USCGC STORIS HAZMAT SURVEY
Attachments:

Mr. Beach and Ms. Dillard,

Encapsulated PCBs (page 1 of the report) become un-encapsulated when a vessel is dismantled, therefore this vessel would not meet the spirit or the terms of the TSCA PCB export ban. Our company would be more than happy to sit down with the USCG and try to determine a cost-effective fashion to dismantle this vessel in the U.S. If we had a facility on the West Coast (and we continue to look), it might, depending upon condition and extent of hazardous material, even be cost-effective to buy the Storis and still dismantle it to meet all U.S. environmental and safety regulations. Even if the US Government had to pay a nominal amount to ensure the vessel met the same fate (i.e. scrapped to U.S. environmental and safety laws and regulations) as the USCG buoy tenders (which are even older) that MARAD is selling for your agency out of the SBRF, it would be better than having this type of mess on the USCG and GSA's hands. Please let us know if we can be of any help; Mr. Boudreaux and Mr. Berry, whom I have cc'd, are EMR Southern Vice Presidents and co-manage the marine division.

Polly Parks
T: +1 (804)410-2168
M: +1 (703)338-6881
F: +1 (804)410-2168
E: polly.parks@emrgroup.com
A: EMR USA – Southern, Washington DC Office, 216 Spotswood Lane, Colonial Beach, VA 22443
usa.emrgroup.com

From: Beach, Jeff L CIV [mailto:Jeff.L.Beach@uscg.mil]
Sent: Fri 10/25/2013 10:21 AM
To: Polly Parks
Cc: 'TONYA.DILLARD@gsa.gov'
Subject: FW: USCGC STORIS HAZMAT SURVEY

Ms. Parks

Per your request the HAZMAT reports for CGC STORIS are attached.

Jeff Beach, CPPM
Manager of Retired CG Boats & Decommissioned Cutters
USCG Headquarters @ ST "E" Campus
(202) 372-3646

-----Original Message-----
From: Beach, Jeff L CIV
Sent: Thursday, October 24, 2013 11:10 AM
To: 'rollins.christopher@epa.gov'
Subject: FW: USCGC STORIS HAZMAT SURVEY

STORIS documentation as requested

Jeff Beach, CPPM

Manager of Retired CG Boats & Decommissioned Cutters
USCG Headquarters @ ST "E" Campus
(202) 372-3646

U.S. Department of Homeland Security

United States Coast Guard

Safety Office, MS#1
U.S. Coast Guard YARD

2401 Hawkins Point Road
Baltimore, MD 21226-1797
Staff Symbol: sm-110
Phone: (410) 636-3772
Fax: (410) 636-3779
Email:
Robert.D.McMenamin@uscg.mil

1/17/2007
5090

MEMORANDUM

From: Robert D. McMenamin
Environmental Protection Specialist

To: Commandant, CG-453

Subj: CGC STORIS HAZMAT CLEAN-UP

1. [redacted]

2. I trust this information will be sufficient for your purposes, but if you have any questions concerning this survey, please contact me.

Robert D McMenamin

ROBERT D MCMENAMIN

Copy: CO, CGC STORIS
Commandant, CG-842
Chief, Planning and Estimating, CG YARD

Levine, Carolyn

From: Levine, Carolyn
Sent: Wednesday, February 05, 2014 5:10 PM
To: 'angie.harrah@mail.house.gov'
Subject: EPA response to October 28, 2013 letter re: Mr. Thomas Wagner's concerns re: USCG Cutter, Storis
Attachments: Boehner-AL-13-000-0576-response.pdf

Hi Angie,

Attached is a response to Mr. Boehner's letter forwarding constituent concerns regarding PCBs on the Cutter, Storis. Please let me know if you have any further questions.
Thank you.

Carolyn Levine
Office of Congressional and Intergovernmental Relations
U.S. EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 05 2014

OFFICE OF
SOLID WASTE AND
EMERGENCY RESPONSE

The Honorable John A. Boehner
Speaker of the House of Representatives
12 South Plum Street
Troy, Ohio 45673

Dear Mr. Speaker:

Thank you for your letter of October 28, 2013, expressing your constituent's concerns regarding whether the presence of polychlorinated biphenyls (PCBs) on the U.S. Coast Guard (USCG) Cutter, Storis, were within levels that would be regulated under the Toxic Substance Control Act (TSCA). I appreciate your interest in this issue.

The portion of TSCA applicable to the export of the Storis are the export restrictions of PCBs. Specifically, TSCA Section 6(e)(3)(A)(ii) and the PCB regulations (40 CFR 761.97) prohibit the export of PCBs greater than or equal to (≥) 50 parts per million (ppm) for disposal (i.e. scrapping) unless an exemption is granted through the rulemaking process outlined under TSCA Section 6(e)(3)(B). To date, no exemptions have been granted for the export of a ship for disposal.

The EPA does not approve ships for export. The ship owner is responsible for compliance with TSCA which means removing and or remediating any shipboard materials that contain PCBs ≥ 50 ppm prior to exporting the vessel for disposal. However, the EPA recently released a technical guidance to assist ship owners in identifying PCBs in concentrations ≥ 50 ppm in shipboard materials before their ships are sold to a non-U.S. Citizen or transferred to a foreign flag registry, prior to export from the United States. This guidance can be found on our website at:
http://www.epa.gov/waste/hazard/tsd/pcbs/pcb_shp_guidnce.htm.

Again, thank you for your letter. If you have further questions, please contact me or your staff may contact Carolyn Levine, in the EPA's Office of Congressional and Intergovernmental Relations at Levine.carolyn@epa.gov or (202) 564-1859.

Sincerely,

Mathy Stanislaus

Mathy Stanislaus
Assistant Administrator

PHIL GINGREY
11TH DISTRICT, GEORGIA
WWW.HOUSE.GOV/GINGREY

1713 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-2931 PHONE
(202) 225-2944 FAX

219 ROSWELL STREET
MARIETTA, GA 30060
(770) 429-1776

600 EAST 1ST STREET
ROME, GA 30161
(706) 290-1776

115 WEST CHEROKEE STREET
CARTERSVILLE, GA 30120
(678) 721-2509

Congress of the United States
House of Representatives
Washington, DC 20515

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEES
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COMMERCE, TRADE, AND CONSUMER PROTECTION

POLICY COMMITTEE

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WWW.DOCTORSCAUCUS.GINGREY.HOUSE.GOV

June 13, 2011

The Honorable Lisa P. Jackson
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20004

Dear Administrator Jackson:

Among the seven priorities that you have set for EPA is Assuring the Safety of Chemicals in our products, our environment, and our bodies. One of my constituents – Chemical Products Corporation (CPC), of Cartersville, Georgia – has requested you to effect timely enforcement of the Toxic Substances Control Act (TSCA) by the EPA so that violators may be restrained and penalized as required by law. CPC believes that it has fully complied with the law, and it is critically important that the EPA enforce this law uniformly.

Under 15 U.S.C. § 2603, the EPA requires certain chemicals to be tested to determine their potential for health and environmental hazards. Among these chemicals is 9,10-Anthracenedione CAS# 84-65-1, commonly known as anthraquinone or AQ for short. CPC has performed all of the required testing of this chemical – at significant expense – and submitted the requisite data to your agency.

CPC believes that several competitors are importing, processing, and/or selling AQ without complying with TSCA. If this is true, CPC faces a competitive disadvantage because it must incur costs not borne by their competitors. On August 18, 2010, CPC provided written notice of these violations to your agency (enclosed) and notified three violators (enclosed). Unfortunately, no action has been taken by the EPA on this matter.

Your urgent attention is needed to uphold this law. I would appreciate it if you would, at your earliest convenience, please review CPC's written notice. If you have any questions, please feel free to contact John O'Keefe in my Marietta, Georgia office at (770) 429-1776.

Sincerely,

Phil Gingrey, M.D.
Member of Congress

Chemical Products Corporation

102 Old Mill Road SE
P.O. Box 2470
Cartersville, Georgia
30120-1692

Phone: 770-382-2144
Fax: 770-386-6053
e-mail: jcook@cpc-us.com

August 18, 2010

Ms. Catherine Roman, Project Manager
U.S. EPA Chemical Information and Testing Branch
Ariel Rios Building, Mail Code 7405M
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460

Subject: Request that EPA enforce its TSCA Test Rule

Dear Ms. Roman;

Three companies have failed or refused to comply with the TSCA test rule published in the March 16, 2006 Federal Register [EPA-HQ-OPPT-2005-0033; FRL-7335-2]. This test rule required testing of 9,10-anthracenedione, CAS No. 84-65-1. These companies have repeatedly and frequently imported 9,10-anthracenedione since 2006 in violation of this TSCA test rule. A review of the docket shows that these companies have not submitted Declarations of Intent to Manufacture by Import or Requests for Exemption from Testing to EPA.

Chemical Products Corporation (CPC) has complied fully with the TSCA test rule and conducted the required testing on 9,10-anthracenedione (see Docket EPA-HQ-OPPT-2005-0033). We ask that EPA immediately take enforcement action against Ponda International, Inc., Heartland Technologies, Inc., and Bastech

because these companies have imported large quantities of 9,10-anthracenedione in violation of the above TSCA test rule, and they have ignored or refused requests from CPC for equitable reimbursement for a portion of CPC's TSCA testing costs. CPC has suffered significant economic hardship as a result of the activities of these three companies.

Imports of 9,10-anthracenedione, CAS number 84-65-1, often called 9,10-anthraquinone or anthraquinone, in violation of the above TSCA test rule continue unabated.

Anthraquinone is specifically designated in the U.S. Harmonized Tariff Code under the category "Quinones"; anthraquinone is specifically assigned number 2914.61.0000. Thus, imports by the following three companies since 2006 of anthraquinone (9,10-anthracenedione), CAS number 84-65-1, are unambiguously documented in U.S. customs records to be:

- Ponda International, Inc. - 23 separate importations totaling more than 2000 metric tons of 9,10-anthracenedione imported
- Heartland Technologies, Inc. - 9 separate importations totaling more than 345 metric tons of 9,10-anthracenedione imported
- Bastech, LLC – 5 separate importations totaling about 145 metric tons of 9,10-anthracenedione imported

You have previously received copies of the letters CPC has sent these three companies seeking reimbursement for testing costs – copies of these letters are also enclosed herein. The owner of Ponda International, Inc., Ms. Yiran Mao, has responded

to CPC's first letter with a handwritten note saying that she owes CPC nothing for testing and then responded to CPC's second letter with a telephone voicemail message to me saying that she does not think that she owes CPC anything. Ponda International, Inc. and the others apparently believe that they can violate the TSCA test rule with impunity and avoid paying an equitable share of the costs to conduct the testing required by the TSCA test rule. We urgently request that EPA take decisive action to enforce its TSCA test rule.

We would greatly appreciate affirmation from you that EPA will take immediate action to enforce the TSCA test rule published in the March 16, 2006 Federal Register. If I can answer any questions concerning this letter or provide further information or documentation, please telephone me at 770-382-2144 or email me at jcook@cpc-us.com.

Sincerely,

Jerry A. Cook

Jerry A. Cook
Technical Director

Enclosures – copies of
2 letters to Ponda International, Inc.
letter to Heartland Technology, Inc.
letter to Bastech, LLC

CHEMICAL PRODUCTS CORPORATION

CARTERSVILLE, GEORGIA 30120

POST OFFICE BOX 2470

TELEPHONE 770-382-2144
FAX 770-386-6053

June 24, 2010

Ms. Yiran Mao
PONDA International
752 Middlefield Road
Palo Alto, CA 94301

Subject: Notice Concerning Possible Violation of TSCA test rule by importation of 9,10-anthracenedione, CAS# 84-65-1 and Request for Reimbursement of costs incurred by Chemical Products Corporation for testing 9,10-anthracenedione (anthraquinone) to satisfy Toxic Substance Control Act of 1976, 15 U.S.C. Sec. 2601, et seq ("TSCA") test rule testing requirements.

Dear Ms. Mao,

On March 16, 2006 EPA promulgated a final test rule under TSCA section 4(a)(1)(B) and 15 U.S.C. section 2603(a)(1)(B)) that required manufacturers and processors of 9,10-anthracenedione (also known by the name anthraquinone), CAS # 84-65-1, to submit to EPA a declaration of intent to manufacture by import prior to importation of 9,10-anthracenedione, along with a statement of intent to conduct the testing required by EPA or an application for exemption from EPA's testing requirements based upon specific criteria.

15 U.S.C. section 2614 states that it is unlawful for any person to fail or refuse to comply with any rule promulgated under section 2603. 15 U.S.C. section 2615 states that any person who violates a provision of section 2614 shall be liable for a civil penalty of up to $25,000 for each violation, with each day a violation continues constituting a separate violation.

Department of Commerce import records list your company as the importer of record for 9,10-anthracenedione (anthraquinone) on the following dates:

CHEMICAL PRODUCTS CORPORATION

DATE	TEU's	DATE	TEU's	DATE	TEU's	DATE	TEU'S	DATE	TEU'S
3/13/2007	8	9/29/2007	8	3/9/2008	10	9/19/2009	8	4/11/2010	10
4/2/2007	8.65	10/27/2007	8	4/2/2008	12	11/9/2009	10	5/8/2010	6
4/9/2007	12.12	1/5/2008	10	5/11/2008	6	2/10/2010	8	5/10/2010	2
4/21/2007	10.38	3/1/2008	10	6/8/2008	8	2/13/2010	4		
5/5/2007	10.39	3/3/2008	10	11/3/2008	10	3/7/2010	6		

1 TEU= 1 20 foot container (approx. 11,000 Kilograms of product)

An examination of the EPA docket for the above test rule (EPA-HQ-OPPT-2005-0033) reveals no evidence that your company has submitted a declaration of intent to manufacture by import or an application for exemption from testing requirements. This may constitute a failure or refusal to comply with EPA's final rule promulgated under 15 U.S.C. section 2603.

Chemical Products Corporation (CPC) submitted a timely statement of intent to conduct the testing required for 9,10-anthracenedione, CAS # 84-65-1. The testing has been completed and the test results, as well as a robust summary, have been submitted to EPA. All other importers of 9,10-anthracenedione during the reimbursement period are liable for payment of a portion of the testing costs incurred by CPC.

It appears that your company may have failed or refused to comply with the above test rule promulgated under 15 U.S.C. 2603(a)(1)(B) and may be subject to civil penalties. Further, your company owes Chemical Products Corporation reimbursement for a portion of the costs we incurred in complying with the EPA's testing requirements.

Please contact us within the next 30 days to arrange payment of an equitable portion of the testing costs that we have incurred.

Thank you,

Jerry A. Cook

Jerry A. Cook
Technical Director

cc: Ms. Catherine Roman, U.S. EPA

CHEMICAL PRODUCTS CORPORATION

CARTERSVILLE, GEORGIA 30120

POST OFFICE BOX 2470

TELEPHONE 770-382-2144
FAX 770-386-6053

June 24, 2010

Ms. Bonnie K. Rumlow
Heartland Technologies Sales of Oshkosh, Inc.
1035 West 19th Avenue
Oshkosh, WI 54902

Subject: Notice Concerning Possible Violation of TSCA test rule by importation of 9,10-anthracenedione, CAS# 84-65-1 and Request for Reimbursement of costs incurred by Chemical Products Corporation for testing 9,10-anthracenedione (anthraquinone) to satisfy Toxic Substance Control Act of 1976, 15 U.S.C. Sec. 2601, et seq ("TSCA") test rule testing requirements.

Dear Ms. Rumlow,

On March 16, 2006 EPA promulgated a final test rule under TSCA section 4(a)(1)(B) and 15 U.S.C. section 2603(a)(1)(B)) that required manufacturers and processors of 9,10-anthracenedione (also known by the name anthraquinone), CAS # 84-65-1, to submit to EPA a declaration of intent to manufacture by import prior to importation of 9,10-anthracenedione, along with a statement of intent to conduct the testing required by EPA or an application for exemption from EPA's testing requirements based upon specific criteria.

15 U.S.C. section 2614 states that it is unlawful for any person to fail or refuse to comply with any rule promulgated under section 2603. 15 U.S.C. section 2615 states that any person who violates a provision of section 2614 shall be liable for a civil penalty of up to $25,000 for each violation, with each day a violation continues constituting a separate violation.

Department of Commerce import records list your company as the importer of record for 9,10-anthracenedione (anthraquinone) on the following dates:

CHEMICAL PRODUCTS CORPORATION

DATE	TEU's	DATE	TEU's
5/19/2008	10	11/21/2009	2
6/15/2008	3.55	1/8/2010	1.78
6/16/2008	6	3/25/2010	1.78
8/28/2009	1.78	5/15/2010	3.56
9/22/2009	1		

1 TEU= 1 20 foot container (approx. 11,000 Kilograms of product)

An examination of the EPA docket for the above test rule (EPA-HQ-OPPT-2005-0033) reveals no evidence that your company has submitted a declaration of intent to manufacture by import or an application for exemption from testing requirements. This may constitute a failure or refusal to comply with EPA's final rule promulgated under 15 U.S.C. section 2603.

Chemical Products Corporation (CPC) submitted a timely statement of intent to conduct the testing required for 9,10-anthracenedione, CAS # 84-65-1. The testing has been completed and the test results, as well as a robust summary, have been submitted to EPA. All other importers of 9,10-anthracenedione during the reimbursement period are liable for payment of a portion of the testing costs incurred by CPC.

It appears that your company may have failed or refused to comply with the above test rule promulgated under 15 U.S.C. 2603(a)(1)(B) and may be subject to civil penalties. Further, your company owes Chemical Products Corporation reimbursement for a portion of the costs we incurred in complying with the EPA's testing requirements.

Please contact us within the next 30 days to arrange payment of an equitable portion of the testing costs that we have incurred.

Thank you,

Jerry A. Cook

Jerry A. Cook
Technical Director

cc: Ms. Catherine Roman, U.S. EPA

CHEMICAL PRODUCTS CORPORATION

CARTERSVILLE, GEORGIA 30120

POST OFFICE BOX 2470

TELEPHONE 770-382-2144
FAX 770-386-6053

June 24, 2010

Mr. Gary Durrant
Bastech, LLC
3211 Powers Avenue
Jacksonville, FL 32207

Subject: Notice Concerning Possible Violation of TSCA test rule by importation of 9,10-anthracenedione, CAS# 84-65-1 and Request for Reimbursement of costs incurred by Chemical Products Corporation for testing 9,10-anthracenedione (anthraquinone) to satisfy Toxic Substance Control Act of 1976, 15 U.S.C. Sec. 2601, et seq ("TSCA") test rule testing requirements.

Dear Mr. Durrant,

On March 16, 2006 EPA promulgated a final test rule under TSCA 4(a)(1)(B) and 15 U.S.C. 2603(a)(1)(B)) that required manufacturers and processors of 9,10-anthracenedione (also known by the name anthraquinone), CAS # 84-65-1, to submit to EPA a declaration of intent to manufacture by import prior to importation of 9,10-anthracenedione, along with a statement of intent to conduct the testing required by EPA or an application for exemption from EPA's testing requirements based upon specific criteria.

15 U.S.C. section 2614 states that it is unlawful for any person to fail or refuse to comply with any rule promulgated under section 2603. 15 U.S.C. section 2615 states that any person who violates a provision of section 2614 shall be liable for a civil penalty of up to $25,000 for each violation, with each day a violation continues constituting a separate violation.

Department of Commerce import records list your company as the importer of record for 9,10-anthracenedione (anthraquinone) on the following dates:

CHEMICAL PRODUCTS CORPORATION

DATE	TEU's
3/3/2007	1.2
3/31/2007	4.68
6/1/2007	3.12
11/12/2007	2
1/13/2008	2

1 TEU= 1 20 foot container (approx. 11,000 kg. of product)

An examination of the EPA docket for the above test rule (EPA-HQ-OPPT-2005-0033) reveals no evidence that your company has submitted a declaration of intent to manufacture by import or an application for exemption from testing requirements. This may constitute a failure or refusal to comply with EPA's final rule promulgated under 15 U.S.C. section 2603.

Chemical Products Corporation (CPC) submitted a timely statement of intent to conduct the testing required for 9,10-anthracenedione, CAS #

84-65-1. The testing has been completed and the test results, as well as a robust summary, have been submitted to EPA. All other importers of 9,10-anthracenedione during the reimbursement period are liable for payment of a portion of the testing costs incurred by CPC.

It appears that your company may have failed or refused to comply with the above test rule promulgated under 15 U.S.C. 2603(a)(1)(B) and may be subject to civil penalties. Further, your company owes Chemical Products Corporation reimbursement for a portion of the costs we incurred in complying with the EPA's testing requirements.

Please contact us within the next 30 days to arrange payment of an equitable portion of the testing costs that we have incurred.

Thank you,

Jerry A. Cook

Jerry A. Cook
Technical Director

cc: Ms. Catherine Roman, U.S. EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 11 2011

ASSISTANT ADMINISTRATOR
FOR ENFORCEMENT AND
COMPLIANCE ASSURANCE

The Honorable Phil Gingrey, M.D.
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Gingrey:

Thank you very much for your letter dated June 13, 2011, to Administrator Jackson relaying Chemical Products Corporation's (CPC) concern with possible noncompliance by its competitors with the Toxic Substances Control Act (TSCA). Because your letter concerns an enforcement-related matter, I have been asked to reply on the Administrator's behalf.

We are very appreciative of CPC's willingness to comply with the applicable TSCA testing requirements and are committed to ensuring that CPC is not at a competitive disadvantage for complying with the law. We also appreciate CPC's concern about industry-wide compliance and its willingness to provide information about its competitors' failure to comply with the TSCA testing requirements for 9,10 Anthracenedione, Chemical Abstract Service Registry Number 84-65-1. I can assure you that EPA is evaluating the information CPC provided and investigating the allegations made by CPC.

Again, thank you for your letter. If you have further questions, please contact me, or your staff may call Carolyn Levine in EPA's Office of Congressional and Intergovernmental Relations at (202) 564-1859.

Sincerely,

Cynthia Giles

BARBARA BOXER

United States Senate

June 18, 2014

Ms. Laura Vaught
Associate Administrator for Congressional and Intergovernmental Relations
Environmental Protection Agency
1200 Pennsylvania Avenue NW Room 3426 Am
Washington, DC 20460-0001

Dear Ms. Vaught:

Enclosed, please find a copy of the correspondence Senator Boxer received from Ms. Jennifer deNicola regarding the Environmental Protection Agency's enforcement of the Toxic Substances Control Act at schools in the Santa Monica Malibu Unified School District.

I am forwarding the attached for your review and consideration. Any information you can provide in response to the concerns expressed by Ms. deNicola will be most appreciated.

Thank you for your assistance in this matter. Please respond to Senator Boxer's Oakland office, attention: Madeline Peare.

Sincerely,

Eric José Vizcaino
Director of Constituent Services

EJV:mp
Enclosure
cc: Ms. Jennifer deNicola

FAX Document

From: Beth Lucas, Malibu Unites

To: Senator Barbara Boxer's Oakland and LA Offices

Oakland fax number: 202-228-6866

LA fax number: 202-224-0357

Re: Attached Letter to Senator Barbara Boxer, Regarding Urgent Need for her assistance with the EPA to enforce TSCA Regarding Carcinogens (PCBS) at the Malibu High School Campus.

Please provide this letter to Senator Boxer and any members of her staff who can help with this really terrible contamination issue that is putting our children, teachers and staff at risk. We have lost almost 10 months with little to no progress and TSCA law violations, so time is of the essence, and we have an EPA representative visiting our school on June 20 – see the attached for more details. We urgently need the Senator's help as per the attached letter. Thank you so much for your help and prompt attention to this urgent and time-critical matter.

4 pages to follow.

Please contact Beth Lucas at 310-456-5151 to confirm receipt. (Please note Jennifer DeNicola, Malibu Unites President is the primary contact and all of her contact info is included at the end of the attached letter.)

Thank you!

Beth A Lucas

1 of 5

06/09/2014 5:57PM (GMT-04:00)

Monday, June 9, 2014

From: Jennifer deNicola, President, Malibu Unites

To: Senator Barbara Boxer

Re: ***Urgent Request for Your Assistance to Direct the EPA to Enforce TSCA Regarding the Carcinogenic Contamination at Malibu High School, Malibu Middle School and Juan Cabrillo Elementary School***

Change.org Petition Tops 1200 Signatures – We Need Your Help!

Dear Honorable Senator Barbara Boxer,

This is an urgent follow-up to our letter to you dated April 29, 2014. Attached is a petition asking for your assistance to direct the EPA to test for and remove PCBs from schools.

This letter requests the following:

1. Please direct the EPA to require testing of all PCB sources
2. Please direct immediate removal of all PCB Sources that violate TSCA's 50ppm threshold at Malibu High School
3. Please direct all schools to use precautionary principals to protect student and teacher health
4. Please urge Malibu High School to remove students from any room or building that has violated TSCA until full testing and remediation has taken place
5. Please sponsor Malibu Unites' "Parents Right to Know Law." Parents have a right to know what toxicants have been discovered at their children's school. This law will expand on the premise of Prop 65, which excludes public schools/buildings.

Intro:

As you are aware, Malibu High School, Malibu Middle School and Juan Cabrillo Elementary School have been dealing with PCBs and pesticides at levels that presented "an unacceptable health risk" since at least 2009 and probably much longer. Because PCBs have been found in window caulk in excess of 50ppm, our school is now under EPA regulation for violation of TSCA. We are having issues with the EPA's method of enforcing TSCA and request your swift assistance to protect our children. As a reminder: three Malibu Middle School teachers were diagnosed with thyroid cancer within four months of each other. Ten others at the school have thyroid disease and many children have complained about health issues as well, in particular, asthma and migraines. The three teachers diagnosed with thyroid cancer currently occupy the classrooms that have tested the highest for PCBs.

205

History:

a. In October 2013, the Santa Monica Malibu Unified School District (SMMUSD) staff moved students and teachers from buildings suspected of PCBs and other toxicants. This occurred when parents and teachers learned that 1,100 tons of contaminated soil had been removed from the middle of campus in the summer of 2011, during summer school session.
b. In November 2013, a small sample of classrooms in these buildings were tested only for PCBs and violated TSCA.
c. In December 2013, SMMUSD told teachers that they should go back to the vacated classrooms after winter break yet before full and complete testing and remediation occurred. Some teachers refused. A few went back without informing parents that their children would be back in rooms with PCBs.
d. It is now June 2014. There has been no further testing and no remediation. There is no approved plan in place to test or remove PCBs. Recommendations from the EPA have not been implemented for Best Management Practices (BMP) cleaning (special note: The EPA has not data to prove that BMP is effective in reducing PCB exposure, yet the EPA is suggesting BMP as a remediation tool)
e. Environ Environmental Corporation, the private environmental firm hired by SMMUSD, took three months to submit a plan to the EPA. Just last week this plan was rejected by the EPA because it did not address PCBs properly nor did it address current TSCA violations.
f. Because of the school district's lack of direction to Environ to fully test and remove PCBs, and Environ's lack of experience in handling PCBs in schools, this process has taken six months longer than expected. Now testing and remediation will not occur this summer and before the next school year begins, exposing children and staff to PCBs for yet another school year. ***This is unacceptable and we need your help!***

We request your urgent assistance at Malibu High School to:

1. Direct the EPA to enforce TSCA Law. PCBs over 50ppm have been found in the small sample of rooms tested. We ask you direct the EPA to require full and comprehensive testing of PCB sources (caulking and other building material), and not rely just on air and wipe samples (which will not solve the PCB problem), throughout MHS and Juan Cabrillo campuses in buildings constructed or renovated between 1950 and 1980.
2. Direct the SMMUSD to identify and test building materials swiftly and comprehensively this summer, prior to the beginning of the next school year (start date Aug 19, 2014) and to ensure a proper remediation plan is required and implemented in a timely manner.
3. If #2 cannot be completed before Aug 19, 2014: Relocate students and teachers from buildings that violate TSCA until full testing to determine the extent of the contamination and remediation has been completed. Temporary classrooms

should be ordered for August for all middle school students and teachers to avoid further exposure in classrooms where the initial violations occurred. Informing parents now of temporary classrooms will prevent a mass exodus from enrollment in August.

Change.org Petition to Remove Cancer Causing PCBs From Our Schools

Shortly after sending you our letter dated April 29, Malibu Unites launched a Change.org petition asking for your swift assistance to direct the EPA to enforce the law as we have noted in the list above.

In a few weeks we have obtained more than 1,200 signatures. The petition supporters are from Malibu, across the country and throughout the world.

Your constituents in Malibu are angry, frightened, horrified, and in disbelief that the school district and the EPA are not putting our children's health above all else, not being precautionary while fixing this problem, are moving so slowly to remedy this issue, that they have not conducted thorough testing to date, that they have spent hundreds of thousands of taxpayer dollars on lawyers to protect their liability but not their students, and that they continue to put our children, teachers and staff at risk. ***We urgently need you use your elected office to help change this.***

For your reference, enclosed is a copy of the petition signatures and a sampling of some of the comments. Please take some time to read these; some of them are heart wrenching.

Request for a meeting and/or site visit

The entire past school year has been wasted while the district has focused on its agenda of protecting its own liability while our children, teachers and staff have been put at unnecessary risk. The district has spent hundreds of thousands of dollars on lawyers rather than testing properly.

MHS parents and members of Malibu Unites have tried to reason with the district and the EPA, with little result. We now desperately need your help to direct the EPA and District to do what more than 1,200 people have so clearly stated: **remove PCBs from the schools and protect our children. We request an in-person meeting with you at your earliest convenience and, if possible, a conference call on or before June 19, 2014 because on June 20, 2014, Jared Blumenfeld, EPA Region 9 Administrator, is scheduled to meet with Malibu Unites and do a "toxic tour" of the school.**

We understand you are extremely busy and your time is precious. But our children's, teachers' and staff's health is also precious. Without your urgent help and intervention, based on events of the past ten months we are concerned that

appropriate actions will not otherwise be taken in a timely manner. This is an opportunity to have a broad, life-changing impact on how this PCB issue is handled by the EPA and the school district to protect our children in Malibu, across California, and throughout the country.

"All Children Deserve a Healthy Environment" – U.S. EPA (website)

Please contact me to set up a meeting.

Thank you for your assistance with this time sensitive, critical issue.

Respectfully Yours,

Jennifer deNicola
Malibu Unites, President
310-848-5400
jen@malibuunites.com

www.MalibuUnites.com
Sign Our Petition to Remove Cancer Causing PCBs from Schools http://goo.gl/sKR30F

5 of 5

AL 14-000-6014

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

February 28, 2014

The Honorable Jim Jones
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Assistant Administrator Jones:

Thank you for appearing before the Subcommittee on Environment and the Economy on Wednesday, November 13, 2013, to testify at the hearing entitled "S. 1009, The Chemical Safety Improvement Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Friday, March 14, 2014. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachment

The Honorable Henry A. Waxman

Transparency has been a significant problem under TSCA. Consumers, public health advocates, researchers, and state governments are often in the dark about chemical risks, even when EPA has data. This is because the statute prohibits EPA from sharing information that has been marked as Confidential Business Information, or CBI, but requires no substantiation of CBI claims. Current law includes no penalty for overclaiming CBI.

The result is a system where the public has no access to any information about approximately 20% of the 83,000 chemicals on the TSCA inventory, and the chemical identities of 66% of new chemicals covered by pre-manufacture notices (PMNs) are marked CBI. EPA has been working to check these CBI claims, and has made significant strides to make more chemical information public, but the process requires significant public resources.

1. Should TSCA reform legislation require upfront substantiation of CBI claims, and why is this important?

S. 1009 would require up front substantiation for some, but not all, CBI claims. The bill contains a long list of types of information that will be presumed to be CBI, without substantiation.

2. Does exempting large categories of information from the substantiation requirement comport with EPA's principles for TSCA reform?

One impact of EPA's review of CBI claims has been a significant decrease in the number of claims being made. For example, under the last Inventory Update Rule, manufacturers claimed that the use of a chemical in children's products was confidential 24% of the time. In the most recent version – the Chemical Data Reporting Rule, the rate of confidentiality claims for the use of a chemical in children's products dropped to 0.4%.

3. Why does EPA collect and publish information about what chemicals are used in children's products?

4. Are there other types of uses that might be particularly relevant and important for the public at large and vulnerable populations?

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable John Shimkus
Chairman
Subcommittee on Environment and the Economy
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Shimkus:

Thank you for the opportunity to respond to the questions for the record following the November 13, 2013, hearing on "S. 1009, The Chemical Safety Improvement Act." Enclosed are the EPA's responses to the questions.

If you have any further questions, please contact me or your staff may contact Sven-Erik Kaiser in my office at kaiser.sven-erik@epa.gov or (202) 566-2753.

Sincerely,

Laura Vaught
Associate Administrator

Enclosure

House Committee on Energy and Commerce
Subcommittee on Environment and Economy
Hearing on "S.1009, The Chemical Safety Improvement Act"
November 13, 2013
Questions for the Record

The Honorable Henry A. Waxman

Transparency has been a significant problem under TSCA. Consumers, public health advocates, researchers, and state governments are often in the dark about chemical risks, even when EPA has data. This is because the statute prohibits EPA from sharing information that has been marked as Confidential Business Information, or CBI, but requires no substantiation of CBI claims. Current law includes no penalty for over claiming CBI.

The result is a system where the public has no access to any information about approximately 20% of the 83,000 chemicals on the TSCA inventory, and the chemical identities of 66% of new chemicals covered by pre-manufacture notices (PMNs) are marked CBI. EPA has been working to check these CBI claims, and has made significant strides to make more chemical information public, but the process requires significant public resources.

Waxman 1. Should TSCA reform legislation require upfront substantiation of CBI claims, and why is this important?

S. 1009 would require up front substantiation for some, but not all, CBI claims. The bill contains a long list of types of information that will be presumed to be CBI, without substantiation.

Response: The Administration's principles for reform of chemicals management legislation state that TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI) and that manufacturers should be required to substantiate their claims of confidentiality. This principle is important to assure transparency and public access to information.

Waxman 2. Does exempting large categories of information from the substantiation requirement comport with EPA's principles for TSCA reform?

Response: As indicated above, the Administration's principles for reform of chemicals management legislation include the need for stronger provisions for transparency and public access to information, including a requirement for the substantiation of confidentiality claims. Stronger provisions on transparency and increased access will ensure that legitimate CBI claims are protected while providing the American public with greater access to chemical information.

The relevant principle states: "TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI). Manufacturers should be required to substantiate their claims of confidentiality. Data relevant to health and safety should not be claimed or otherwise treated as CBI. EPA should be able to negotiate with other governments (local, state, and foreign) on

appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety."

One impact of EPA's review of CBI claims has been a significant decrease in the number of claims being made. For example, under the last Inventory Update Rule, manufacturers claimed that the use of a chemical in children's products was confidential 24% of the time. In the most recent version – the Chemical Data Reporting Rule, the rate of confidentiality claims for the use of a chemical in children's products dropped to 0.4%.

Waxman 3. Why does the EPA collect and publish information about what chemicals are used in children's products?

Waxman 4. Are there other types of uses that might be particularly relevant and important for the public at large and vulnerable populations?

Response to Questions 3 and 4: Chemical Data Reporting (CDR) information is used by the EPA to support risk screening, assessment, priority setting and management activities. Processing and use information reported in 2012 will help the EPA screen and prioritize chemicals for the purpose of identifying potential human health and environmental effects. Collecting the information every four years will assure that the public has timely access to current and improved data. This information will also provide the public with greater access to a wide range of information on those chemicals that are produced in large quantities. Improved data will enhance the agency's ability to more effectively identify and address potential chemical risks.

The 2012 CDR collected information on more than 7,600 chemicals in commerce including information on more than 350 chemicals used in children's products such as toys, playground and sporting equipment, arts and crafts materials, and furniture. In addition, manufacturers reported on more than 1,700 chemicals used in consumer products generally. Users of the CDR data are able to view chemicals with commercial and consumer uses and by geographic area for facilities where chemicals are being manufactured. This information helps inform potential exposures and would be relevant for the public and vulnerable populations.

For additional information on the 2012 CDR, see the Federal Register Notice for 2012 CDR reporting at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0187-0393.

AL 12-001-3340

QUESTIONS FOR THE RECORD
FOR SVEN-ERIK KAISER, ENVIRONMENTAL PROTECTION AGENCY, HEARING ON "ARE CONSMERS ADEQUATELY PROTECTED FROM FLAMMABILITY OF UPHOLSTERED FURNITURE? HEARING ON THE FURNITURE FLAMMABILITY STANDARDS AND FLAME RETARDANT CHEMICALS
SENATE APPROPRIATIONS SUBCOMMITTEE ON FINANCIAL SERVICES AND GENERAL GOVERNMENT
JULY 17, 2012

Senator Richard J. Durbin, Chairman

Flame Retardant Chemicals

Question: TDCP is the chlorinated version of a chemical known as 'tris' that the CPSC attempted to ban from children's sleepwear in the late 1970s after it was found to be carcinogenic. Despite its similarity to tris, TDCP is a widely used flame retardant in furniture cushions and baby products. Along with components of Firemaster 550, EPA has placed a chlorinated flame retardant, TCEP, on a list of chemicals that will be reviewed next year under its TSCA work plan. However, EPA did not place TDCP on the list. Why not?

Answer:

Question: Polybrominated diphenyl ethers, or PBDEs, are a large class of flame retardant chemicals that have been shown to be harmful to humans and the environment. What can be done to remove products with these chemicals from American homes and properly dispose of them?

Answer:

Future Efforts Regarding Flame Retardants

Question: EPA has started a new plan to re-evaluate all of the flame retardants on the market with the latest testing and analysis methods to see if any of these chemicals poses a risk to the public's health. Once you've completed the new plan, what will the next steps be?

Answer:

Europe Bans or Greatly Restricts Flame Retardants

Question: Furniture flammability is not just an issue here in the United States. However, many European countries have taken alternative steps to ensure flammability standards can be met without causing public health concerns. The United Kingdom has banned the use of conventional, flexible polyurethane foams in the manufacture of upholstered furniture for sale. In addition, many European countries have banned the use of PDBEs and greatly restricted other flame retardant chemicals. Does EPA examine how other countries are regulating flame

retardant chemicals?

Answer:

Question: Could any of these methods be applied here in the United States?

Answer:

Toxic Substances Control Act (TSCA)

Question: Following the series of articles in the *Chicago Tribune* that highlighted the potential health risk of flame retardant chemicals, many of my constituents responded that the Federal Government should have protected the public from these chemicals. What steps has EPA taken outside of legislation to more effectively regulate hazardous chemicals such as flame retardants?

Answer:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Richard J. Durbin
Chairman
Subcommittee on Financial Services and General Government
Senate Appropriations Committee
United States Senate
Washington, D.C. 20510-6175

Dear Chairman Durbin:

Thank you for the opportunity to respond to the questions for the record following the July 17, 2012 hearing on "Are Consumers Adequately Protected from Flammability of Upholstered Furniture." The attached document has responses to the questions. I hope that this information is useful to you and the members of the committee.

If you have any further questions, please contact me or your staff may call Sven-Erik Kaiser in my office at (202) 566-2753.

Sincerely,

Arvin Ganesan
Associate Administrator

Attachment

Senate Appropriations Committee
Subcommittee on Financial Services and General Government
Hearing on "Are Consumers Adequately Protected from Flammability of Upholstered Furniture"
Questions for the Record
Jim Jones, Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
July 17, 2012

Senator Richard J. Durbin, Chairman

Flame Retardant Chemicals

Durbin 1. TDCP is the chlorinated version of a chemical known as 'tris' that the CPSC attempted to ban from children's sleepwear in the late 1970s after it was found to be carcinogenic. Despite its similarity to tris, TDCP is a widely used flame retardant in furniture cushions and baby products. Along with components of Firemaster 550, EPA has placed a chlorinated flame retardant, TCEP, on a list of chemicals that will be reviewed next year under its TSCA work plan. However, EPA did not place TDCP on the list. Why not?

Answer: In March 2012, following the development of the "TSCA Work Plan Chemicals: Methods Document", a screening process to identify chemicals for review based on their combined hazard, exposure, persistence, and bioaccumulation characteristics, the EPA identified 83 work plan chemicals for risk assessment under the Toxic Substances Control Act. [1] Of these, an initial seven chemicals were identified for risk assessment development in 2012.[2] Although TDCP has chemical characteristics similar to other flame retardants, it did not meet any of the specific listing criteria identified in the TSCA Work Plan methods document. Specifically, it was not identified as a known or probable human carcinogen by the Integrated Risk Information System, International Agency for Research on Cancer, or National Toxicology Program, and was not reported as being in children's products through the 2006 Information Use Reporting or the Washington State Children's List. Consumer products were not a screening category for Step 1 in the Work Plan development process.

On June 1, 2012, the EPA identified 18 additional chemicals from the TSCA Work Plan, which the agency intends to review and for which the agency will develop risk assessments in 2013 and 2014, including three flame retardant chemicals: Bis(2-Ethylhexyl)-3,4,5,6-tetrabromophthalate (TBPH); 2-Ethylhexyl-2,3,4,5-tetrabromobenzoate (TBB); and Tris(2-chloroethyl)phosphate (TCEP).[3] The EPA is currently developing a strategy, scheduled for completion by the end of this year, to address these three flame retardant chemicals as well as a broader set of flame retardant chemicals. This effort will assist the agency in focusing risk assessments on those flame retardant chemicals that pose the greatest potential concerns. The EPA anticipates initiating the risk assessments in this category of chemicals in 2013.

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[1] http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf
[2] http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html#2012
[3] http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html#2013

Durbin 2. Polybrominated diphenyl ethers, or PBDEs, are a large class of flame retardant chemicals that have been shown to be harmful to humans and the environment. What can be done to remove products with these chemicals from American homes and properly dispose of them?

Answer: The EPA's regulatory efforts for addressing concerns with PBDEs include a Significant New Use Rule issued in 2006, a recently proposed SNUR, and a proposed Test Rule for PBDEs. The agency has also engaged producers and importers in negotiations and commitments to voluntarily phase out certain PBDEs.

In 2003, the sole U.S. manufacturer agreed to voluntarily phase out production of pentaBDE and octaBDE by December 31, 2004. In conjunction with this phase out, the EPA issued a SNUR in 2006 which designated the manufacture and import of six PBDE compounds as a significant new use. The SNUR required persons who intended to manufacture or import tetra-, penta-, hexa-, hepta-, octa- and nonaBDE to submit information to the EPA for review before engaging in the new use. Additionally, the SNUR ensured that no new manufacture or import of pentaBDE or octaBDE could occur after January 1, 2005.

Following negotiations with the EPA in 2009, the sole importer and two domestic manufacturers of decaBDE voluntarily agreed to stop producing decaBDE by December 31, 2012, for all uses except certain military and transportation uses, and to stop providing decaBDE for all uses by December 31, 2013. On April 2, 2012, the EPA proposed to amend the 2006 SNUR by expanding the scope to include processors of PBDEs and articles containing PBDEs. The proposed amended SNUR would also designate the manufacturing, importing, and processing of decaBDE, including in articles, as significant new uses. Along with the proposed SNUR, the EPA also proposed a test rule for those persons that manufactured, imported, or processed commercial PBDEs after December 31, 2013. With a test rule in effect, manufacturers, importers and processors could be required to conduct health and safety studies to inform data gaps.

To aid companies in moving to safer alternatives, the EPA recently published, with public participation through its Design for the Environment program, a draft report: "An Alternatives Assessment for the Flame-Retardant Decabromodiphenyl Ether." Public comments were due by September 30, 2012, and the EPA expects to finalize the report in the coming months.[4]

While these efforts may result in a reduction of products containing PBDEs in American homes, we would note that the Consumer Product Safety Commission has authority to require recalls if it determines that a product presents an unreasonable risk of injury or death. The EPA is not aware of CPSC requiring a recall of furniture as a result of the product containing PBDE. In terms of disposal, PBDE-containing furniture can be disposed of in municipal solid waste landfills.

[4] http://www.epa.gov/dfe/pubs/projects/decaBDE/about.htm

Future Efforts Regarding Flame Retardants

Durbin 3: EPA has started a new plan to re-evaluate all of the flame retardants on the market with the latest testing and analysis methods to see if any of these chemicals poses a risk to the public's health. Once you've completed the new plan, what will the next steps be?

Answer: As indicated in the response to question one, the agency is currently developing a strategy, scheduled for completion by the end of this year, on the three flame retardant chemicals identified earlier this year, as well as on a broader set of brominated flame retardant chemicals. The strategy will assist the EPA in focusing its risk assessments efforts on those flame retardant chemicals that appear to pose the greatest potential concerns. The EPA anticipates initiating the risk assessments on brominated flame retardants in 2013. If an assessment indicates significant risk, the EPA will evaluate and pursue appropriate risk reduction actions. If an assessment indicates no significant risk, the EPA will conclude its current work on that chemical.

Europe Bans or Greatly Restricts Flame Retardants

Durbin 4: Furniture flammability is not just an issue here in the United States. However, many European countries have taken alternative steps to ensure flammability standards can be met without causing public health concerns. The United Kingdom has banned the use of conventional, flexible polyurethane foams in the manufacture of upholstered furniture for sale. In addition, many European countries have banned the use of PDBEs and greatly restricted other flame retardant chemicals. Does EPA examine how other countries are regulating flame retardant chemicals?

Durbin 5: Could any of these methods be applied here in the United States?

Answer to #4 and #5: The EPA is aware of what other countries are doing on flame retardants and will consider any data or assessments that are available to us. The EPA's authority for regulating PBDEs and other industrial chemicals must be consistent with TSCA, this country's chemicals management legislation. While TSCA provides the authority to take action to prohibit or limit the manufacture, import, or use of a chemical, the requirements needed to take that action have proven very challenging.

The Consumer Product Safety Commission also encourages the use of barriers to reduce the use or need for chemical flame retardants while still meeting, or exceeding flammability standards. In 2006, the CPSC published a regulation on the allowable rate of heat release from a mattress;[5] this has effectively reduced both the size and growth rate of fires in mattresses that were in compliance with the new standard. Additionally, in 2008, the CPSC proposed a rule establishing flammability standards on the smolder propensity of upholstered furniture.[6]

[5] http://www.cpsc.gov/businfo/frnotices/fr06/mattsets.pdf
[6] http://www.cpsc.gov/businfo/frnotices/fr08/furnflamm.pdf

Toxic Substances Control Act (TSCA)

Durbin 6. Following the series of articles in the Chicago Tribune that highlighted the potential health risk of flame retardant chemicals, many of my constituents responded that the Federal Government should have protected the public from these chemicals. What steps has EPA taken outside of legislation to more effectively regulate hazardous chemicals such as flame retardants?

Answer: The EPA engaged in negotiations in 2003 and again in 2009 with manufacturers and importers of PBDEs. The agency considers commitments from chemical companies to voluntarily phase out certain chemicals from the market an important strategy of chemical management. The EPA is using SNURs to ensure if any PBDEs that have been voluntarily phased out were to be reintroduced into commerce, they would first be subject to EPA's review.

In addition to those actions, the EPA believes that its current approach to identifying chemicals for review and assessment utilizing the "TSCA Work Plan Chemicals: Methods Document", is a significant step to ensuring the safe use of chemicals. If, through this process, the EPA identifies chemicals that pose a concern, the agency will evaluate and pursue appropriate risk reduction actions, as warranted, using existing TSCA authority. If an assessment indicates no significant risk, the EPA will conclude its current work on that chemical. However, identification of chemicals as Work Plan Chemicals does not mean that EPA would not consider other chemicals for risk assessment and potential risk management action under TSCA and other statutes. EPA will consider other chemicals if warranted by available information. EPA will also continue to use its TSCA information collection, testing, and subpoena authorities, including sections 4, 8, and 11(c) of TSCA, to develop needed information on additional chemicals that currently have less robust hazard or exposure data.[7]

[7] http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html#not

AR-10-000-4465

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

JOE BARTON, TEXAS
RANKING MEMBER

ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225-2927
Minority (202) 225-3641

March 23, 2010

James Jones
Deputy Assistant Administrator
Office of Prevention, Pesticides and Toxic Substances
US Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Mr. Jones:

Thank you for appearing before the Subcommittee on Commerce, Trade, and Consumer Protection on March 4, 2010, at the hearing entitled "TSCA and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions."

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions.

Please provide your responses by April 9, 2010, to Earley Green, Chief Clerk, via e-mail to Earley.Green@mail.house.gov. Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,

Henry A. Waxman
Chairman

Attachment

The Honorable Bobby L. Rush

1. Biomonitoring can be used to determine the amount that people are actually exposed to certain chemicals. At our last hearing on TSCA in November, we heard from the Centers for Disease Control and Prevention about their biomonitoring program. Their fourth biomonitoring report found "widespread" exposure to emerging chemicals of concern. These include PBTs such as perfluorinated compounds (PFOA) and flame retardants (PBDEs).

    a. Do you believe that if a chemical is found to contaminate the human body, there is exposure?

    b. Do you believe once we know that a chemical is a PBT and there is exposure, this is sufficient information for EPA to take immediate action to reduce or eliminate the use of PBTs?

    c. If we know that something is a PBT but we do not know if there is exposure, does EPA think it would be a priority to find out if there is exposure? Can EPA act on PBTs without exposure information?

    d. Do you believe newly developed chemicals that meet the criteria for being a PBT should be restricted from entering commerce?

    e. When there is known exposure to a persistent and bioaccumulative chemical but toxicity is not known, do you believe that this chemical should be limited in commerce or prioritized for toxicity testing?

2. The National Research Council in a 2005 report has found biomonitoring to be a "tool with great potential," and the GAO recently testified that EPA has not sufficiently used available biomonitoring data in its chemical risk assessments.

    a. Does EPA consider the presence of persistent and bioaccumulative chemicals in the human body to be a trigger for toxicity testing or risk mitigation?

    b. Does EPA have a plan for utilizing biomonitoring data for identification of exposure to persistent and bioaccumulative chemicals?

3. Mr. Jones, we heard you describe what the EPA is currently doing on PBTs. However, EPA drafted a document in 1998 entitled "Multimedia Strategy for Priority Persistent, Bioaccumulative, and Toxic (PBT) Chemicals." In the years since, it does not appear that that draft document was ever finalized.

    a. Is there a plan under this Administration to finalize this strategy document? Similarly, EPA's website says that the PBT program is no longer active. Can you elaborate on this? Do the new chemical action plans you explained in your testimony replace this older PBT program?

4. EPA's recently announced action plans on 4 chemicals included 3 PBTs.

   a. Do you have any indication how many more chemical action plans in the pipeline will be for PBTs? You have action plans for non-PBTs. With limited resources, is there a preference given to PBTs for an action plan?

   b. How many actions plans should we expect in total?

   c. How many PBTs are currently being used in commerce? How many PBTs are no longer used in commerce, yet are still contaminating the environment and our bodies?

   d. Does EPA know how many new PBTs have entered into commerce since TSCA was enacted in 1976?

5. Mr. Sturdevant emphasized the need to transition towards safer alternatives where PBTs are currently used in commerce. To determine safety, we need information on a chemical's toxicity. Currently, EPA is limited in its ability to get this information.

   a. Is there a process in place at EPA to require or encourage switching to safer alternatives, as suggested by Mr. Sturdevant?

The Honorable Ed Whitfield

1. During questioning, I asked what the process was for adding chemicals to the TRI list. Please state for the record what that process is.

2. How does a chemical, like Metiran, which the toxicity test showed was not causing a problem in animals, make the list?

3. Please state whether chemicals have been statutorily added to the TRI. Please state whether any of their toxicity profiles are similar to or more benign than that for Metiran.

4. Please provide a full explanation of the steps EPA must take to ban a PBT. Please state whether there are legal authorities other than TSCA to address PBT chemical risks.

The Honorable Joe Barton

1. Please state whether the U.S. EPA was the source for recognition and inclusion of Article 3.3 in the Stockholm Convention concerning new chemicals with POPs characteristics. If not, please explain why this fact was stated in EPA's notice finalizing existing U.S. PBT policy.

2. Please state whether EPA's policy for new PBT chemicals followed a foreign policy or was the first of its kind internationally.

3. Has the existing PBT policy been effective -- in that companies have avoided the development and submission of new chemical PBTs except in cases where the exposures and releases were carefully controlled or avoided entirely?

4. On Thursday, February 4, 2010, U.S. EPA deleted its web pages specifically designed to address PBT issues. Apparently, the Agency did this to archive materials that were as old as 2002. However, the "archive" contains materials newer than 2002. Please explain why those materials newer than the archive guidelines were archived and what criteria were used in determining which materials to archive.

5. EPA's web page states "The PBT program is no longer active." Please explain this statement and whether it means EPA no longer supports its new chemicals PBT policy.

6. Other than taking down the PBT website, please describe what actions the Obama Administration has taken to demonstrate its support for the Sustainable Futures effort. Please describe what improvements, if any, have occurred on your watch.

7. Work on implementing the Stockholm POPs Convention has progressed since the Convention entered into force. Despite EPA Administrator Whitman, in May 2001, making the United States a signatory to this Convention by signing the agreement, the United States Senate has not ratified the agreement, and Congress has not approved the necessary statutory changes to TSCA and FIFRA required to fully implement the treaty obligations.

    a. Please describe the U.S. government's experience with implementation of the Convention since it entered into force.
    b. Please state whether the new chemical listing process has proceeded as the United States anticipated under the treaty as negotiated.
    c. Please state whether the treaty as implemented has changed in any respect from the treaty as negotiated by the United States.

8. EPA established a PMN policy with respect to new PBT chemicals in 1999.

    a. Please explain the Agency's experience implementing that policy.
    b. Please state the number of new PBT substances that have been introduced into commerce since 1999.
    c. Please describe the risk management measures, if any, the Agency required for those substances.
    d. Please state whether the PMN policies have been effective in minimizing or eliminating risks to human health or the environment, and if so, how.

9. Please describe any steps the Agency is taking to address the findings of the 2008 Society of Environmental Toxicology and Chemistry's Pellston Workshop on PBT characteristics. Please also describe how the Agency is incorporating the developing science and better identifying PBT substances identified by that Pellston workshop, the goal of which was to improve the process of identification and evaluation of chemicals against the PBT criteria.

10. Please describe the impact of EPA's New Chemicals PBT Policy on the number of new PBT chemicals. Of the new PBT chemicals of which EPA has been notified, please state the general trend for release of these chemicals into the environment?

11. Your testimony references EPA's PBT profiler tool, which I have been told was designed largely for industry's use in designing safer/greener new chemicals. Please generally identify the primary users of this tool and describe the benefits derived from that use.

12. In responding to a question from Representative Whitfield on the difference in legal standards between TSCA chemicals and FIFRA pesticides, you mentioned the pesticide standard of "reasonable certainty of no harm". Please state whether there are distinct differences between routes of exposure for pesticides, governed under FIFRA, versus other chemicals which could be subject to TSCA.

EPA RESPONSES TO CONGRESSIONAL QUESTIONS FOR THE RECORD
March 4, 2010 PBT Hearing
House Energy and Commerce
Sub-Committee on Commerce, Trade, and Consumer Protection

September 15, 2010

The Honorable Bobby L. Rush

1. Biomonitoring can be used to determine the amount that people are actually exposed to certain chemicals. At our last hearing on TSCA in November, we heard from the Centers for Disease Control and Prevention about their biomonitoring program. Their fourth biomonitoring report found "widespread" exposure to emerging chemicals of concern. These include PBTs such as perfluorinated compounds (PFOA) and flame retardants (PBDEs).

a. Do you believe that if a chemical is found to contaminate the human body, there is exposure?

Yes, although presence in the body alone does not tell us what the resulting risk of the chemical may be to human health. The presence of a chemical in the human body is a key factor in Agency decision making regarding both toxicity testing and risk mitigation of chemicals. A number of the Agency's risk reduction actions under TSCA have been focused on chemicals found in the human body in biomonitoring studies, for example, penta- and octa-bromodiphenyl ether as well as a broad class of PFOS and PFAC chemicals. Biomonitoring information is also a selection criterion for the new EPA chemical action plans recently released, and action plans where this was a factor include polybrominated diphenyl ethers, phthalates, long-chain perfluorinated compounds and short chain chlorinated paraffins.

b. Do you believe once we know that a chemical is a PBT and there is exposure, this is sufficient information for EPA to take immediate action to reduce or eliminate the use of PBTs?

Exposure to a PBT is potential cause for concern, although presence in the body alone does not tell us what the resulting risk of the chemical may be to human health, Having said that, as a result of the legal hurdles and procedural requirements TSCA places on EPA prior to collecting data, there are large, troubling gaps in the available data and state of knowledge on many widely used chemicals in commerce. Although there is a review process for new chemicals being introduced into commerce, chemical producers are not required to provide, without further action from EPA, the data necessary to fully assess a chemical's risks.

In the cases where EPA has adequate data on a chemical, and wants to protect the public against well-known risks to human health and the environment, there are legal hurdles that prevent quick and effective regulatory action. Meanwhile, the public may be exposed to chemicals for which we have little understanding of the consequences.

When Administrator Jackson announced that EPA would be taking action on a number of chemicals, she noted criteria EPA would use to identify these chemicals.[1] PBT characteristics were among those criteria. In fact, three of the four chemical groups selected for the initial group of action plans were PBTs.

c. If we know that something is a PBT but we do not know if there is exposure, does EPA think it would be a priority to find out if there is exposure? Can EPA act on PBTs without exposure information?

Persistence and bioaccumulation, as well as toxicity, are certainly very important factors in evaluating a chemical's risks. Filling in gaps in exposure information for PBTs would be a high priority. Currently, under TSCA, exposure information is necessary to determine whether an existing chemical presents or may present an unreasonable risk. The response to the following question outlines EPA's Policy Statement for the consideration of PBTs during the review of new chemicals under TSCA.

d. Do you believe newly developed chemicals that meet the criteria for being a PBT should be restricted from entering commerce?

As outlined in the Administration's principles on TSCA reform, we believe that chemicals should be reviewed against safety standards that reflect risk-based criteria protective of human health and the environment, and that EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard.

That a chemical is persistent and bioaccumulative, as well as toxic, is certainly a very important factor in evaluating a chemical's risks and prioritizing chemicals for action. PBT characteristics are among the factors the Agency has considered in identifying chemical substances for action in both its enhanced existing chemicals management program and its new chemicals program.

Beginning in 1988, EPA first used its accumulated experience to group certain chemical substances with similar physicochemical, structural, and toxicological properties into categories to enable both Pre-Manufacture Notice (PMN) submitters and EPA reviewers to benefit from

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[1] http://www.epa.gov/oppt/existingchemicals/pubs/Existing.Chem.Fact.sheet.pdf

the accumulated data and decisional precedents for the assessment and regulation of new chemical substances. In 1999 (Federal Register, 11/4/1999, page 60194-60204), EPA issued a final policy statement regarding the category of persistent, bioaccumulative, and toxic (PBT) new chemical substances. Through the Policy Statement, EPA adopted specific identification criteria and the associated process that EPA would use in evaluating new chemical substances suspected as being persistent bioaccumulators. The Policy Statement made clear to submitters of new chemical notifications under TSCA section 5 that substances meeting these criteria may need to undergo testing on "P" and "B" endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify "PBT chemical substances." In addition, the Policy Statement made clear that control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern.

e. When there is known exposure to a persistent and bioaccumulative chemical but toxicity is not known, do you believe that this chemical should be limited in commerce or prioritized for toxicity testing?

There are large, troubling gaps in the available data and state of knowledge on many widely used chemicals in commerce. Although there is a review process for new chemicals being introduced into commerce, chemical producers are not required to provide, without further action from EPA, the data necessary to fully assess a chemical's risks. If toxicity is unknown for chemicals known to be persistent and bioaccumulative, this would be an important data gap which should be filled.

As outlined in the Administration's principles on TSCA reform, we believe that chemicals should be reviewed against safety standards that reflect risk-based criteria protective of human health and the environment, and that EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard.

2. The National Research Council in a 2005 report has found biomonitoring to be a "tool with great potential," and the GAO recently testified that EPA has not sufficiently used available biomonitoring data in its chemical risk assessments.

a. Does EPA consider the presence of persistent and bioaccumulative chemicals in the human body to be a trigger for toxicity testing or risk mitigation?

That a chemical is persistent and bioaccumulative, as well as toxic, is certainly a very important factor in evaluating a chemical's risks. When Administrator Jackson announced that EPA would

be taking action on a number of chemicals, she noted criteria EPA would use to identify these chemicals.[2] PBT characteristics were among those criteria.

EPA has used persistence, bioaccumulation, and toxicity (PBT) characteristics in determining toxicity testing needs and risk mitigation activities in the New Chemical Program for over 20 years. Beginning in 1988, EPA first used its accumulated experience to group certain chemical substances with similar physicochemical, structural, and toxicological properties into categories to enable both PMN submitters and EPA reviewers to benefit from the accumulated data and decisional precedents for the assessment and regulation of new chemical substances. In 1999 (Federal Register, 11/4/1999, page 60194-60204), EPA issued a final policy statement regarding the category of persistent, bioaccumulative, and toxic (PBT) new chemical substances. Through the Policy Statement, EPA adopted specific identification criteria and the associated process that EPA would use in evaluating new chemical substances suspected as being persistent bioaccumulators. The Policy Statement made clear to submitters of new chemical notifications under TSCA section 5 that substances meeting these criteria may need to undergo testing on "P" and "B" endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify "PBT chemical substances." In addition, the Policy Statement made clear that control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern.

More recently, EPA has had the opportunity to incorporate biomonitoring information in conjunction with PBT information in the Existing Chemical Program. In 2005, EPA's Science Advisory Board reviewed a draft risk assessment of perfluorooctanoic acid (PFOA). This assessment was one of the first examples of the use of human biomonitoring and pharmacokinetic modeling in assessing potential human risks, and in fact was highlighted in NRC 2006 report on biomonitoring. The biomonitoring information, in conjunction with the PBT characteristics of PFOA, formed the rationale for the risk mitigation activities and the phase-out of PFOA (as well as the earlier phase out of PFOS). In addition, this information has formed the basis for the toxicity testing requirements, and risk mitigation activities, of all new perfluoro compounds submitted through the PMN program. In September 2009, EPA announced efforts to enhance the Agency's current chemical management progam, which includes the development and release of chemical specific action plans. To date, the Agency has released five action plans, including several chemicals which were selected, in part, on biomonitoring information, and/or known PBT properties, including perfluoroalkyl acids, PBDEs, BPA, and phthalates.

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[2] http://www.epa.gov/oppt/existingchemicals/pubs/Existing.Chem.Fact.sheet.pdf

b. Does EPA have a plan for utilizing biomonitoring data for identification of exposure to persistent and bioaccumulative chemicals?

Characteristics of persistence and bioaccumulation and biomonitoring data are among the factors the Agency has considered in identifying chemical substances for action in its enhanced existing chemicals management program and will continue to use these factors. In addition, the Great Lakes Restoration Initiative (GLRI) is undertaking a biomonitoring study of intensive Great Lakes fish consumers with a focus on chemicals of emerging concern such as brominated flame retardants and perfluorinated compounds. The GLRI is a five year multi-agency effort to restore and maintain the chemical, physical, and biological integrity of the Great Lakes. Under the GLRI, significant new investments are being made to address PBTs, including pollution prevention efforts, such as implementation of the Great Lakes Regional Collaboration Mercury in Products and Waste Phase-down Strategy, as well as in green chemistry and product stewardship activities in the Great Lakes basin. Efforts include further monitoring and surveillance for new and emerging chemicals in the Great Lakes through expanded fish and air deposition monitoring and a new sediment core program to help identify new chemical toxicants which may pose threats to human health and the environment.[3]

3. Mr. Jones, we heard you describe what the EPA is currently doing on PBTs. However, EPA drafted a document in 1998 entitled "Multimedia Strategy for Priority Persistent, Bioaccumulative, and Toxic (PBT) Chemicals." In the years since, it does not appear that that draft document was ever finalized.

a. Is there a plan under this Administration to finalize this strategy document? Similarly, EPA's website says that the PBT program is no longer active. Can you elaborate on this? Do the new chemical action plans you explained in your testimony replace this older PBT program?

EPA does not intend to finalize this document. EPA's current enhanced existing chemicals program, which includes the development and implementation of action plans for chemicals that EPA believes may pose environmental or public health concerns, has superseded this program. Persistence and bioaccumulation, as well as toxicity, are very important factors in evaluating a chemical's risks.

4. EPA's recently announced action plans on 4 chemicals included 3 PBTs.

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[3] http://greatlakesrestoration.us/

a. Do you have any indication how many more chemical action plans in the pipeline will be for PBTs? You have action plans for non-PBTs. With limited resources, is there a preference given to PBTs for an action plan?

At this point, we cannot say how many future action plans may address PBTs. Persistence and bioaccumulation, as well as toxicity, are very important factors in evaluating a chemical's risks.

b. How many actions plans should we expect in total?

As of August 20, 2010, EPA has made public eight chemical specific action plans. EPA will continue to address chemicals that EPA believes may pose environmental or public health concerns.

c. How many PBTs are currently being used in commerce? How many PBTs are no longer used in commerce, yet are still contaminating the environment and our bodies?

We do not know exactly how many exist and their status in commerce. There are more than 84,000 chemicals on the TSCA Inventory, and the Inventory does not include pesticides and other chemicals subject to other statutes. EPA does, however, have information on some new and existing TSCA chemicals. Starting in Fiscal Year 2001, about 6% of all New Chemical notices have been determined to be PBTs. About 2% of more than 2200 existing chemicals in the High Production Volume Challenge program were identified as PBTs using EPA's PBT Profiler screening tool and the new chemicals program protocols.

d. Does EPA know how many new PBTs have entered into commerce since TSCA was enacted in 1976?

The Agency did not begin tracking PBTs until Fiscal Year 2001. Starting in 2001, about 6% of all New Chemical notices have been determined to be PBTs, for a total of 680 through 2008. There does not seem to be a discernible trend that we can identify, but the range is from a low of 56 in 2008 to a high of 109 in 2002.

5. Mr. Sturdevant emphasized the need to transition towards safer alternatives where PBTs are currently used in commerce. To determine safety, we need information on a chemical's toxicity. Currently, EPA is limited in its ability to get this information.

a. Is there a process in place at EPA to require or encourage switching to safer alternatives, as suggested by Mr. Sturdevant?

The Design for the Environment (DfE) Program in EPA pursues two different approaches to promote the transition from chemicals that may pose environmental or public health concerns, including PBTs, to scientifically proven safer alternatives. Under the first approach, the

Program conducts the Safer Product Labeling program to encourage formulators of cleaning and other products to reformulate away from chemicals that may pose environmental or public health concerns towards safer substitutes. The Program uses the Agency's toxicological, chemistry and other scientific expertise to screen chemicals and recommend safer replacements. Products which meet the criteria for every chemical ingredient in the product are allowed to affix a DfE logo to their product asserting safer chemistry.[4]

When safer alternative chemicals are not readily available or not widely used in an industry, DfE uses a different approach, named Alternatives Assessment, to identify and evaluate safer chemicals. These Alternatives Assessments are a collaborative effort with leaders in industry, NGOs, agency scientists and, as appropriate, academic or other stakeholders. Agency science is used to understand the potential for environmental and human health impacts of the alternatives and enable a move to safer chemicals.

The Honorable Ed Whitfield

1. During questioning, I asked what the process was for adding chemicals to the TRI list. Please state for the record what that process is.

The toxic chemicals subject to the TRI requirements are those chemicals on the list in Committee Print Number 99–169 of the Senate Committee on Environment and Public Works, titled "Toxic Chemicals Subject to Section 313 of the Emergency Planning and Community Right-To-Know Act of 1986" and any revisions to the list as may be made pursuant to subsection (d) or (e) of Section 313. The current list has over 600 individually listed chemicals and about 30 chemicals categories.

EPCRA 313(d) provides the authority to add a chemical to the TRI list if the Administrator determines, in his or her judgment and based on available and generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies, that there is sufficient evidence to establish any one of the following:

- The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.

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[4] http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm.

- The chemical is known to cause, or can reasonably be anticipated to cause in humans (1) cancer or teratogenic effects, or (2) serious or irreversible reproductive dysfunctions, neurological disorders, heritable genetic mutations, or other chronic health effects.

- The chemical is known to cause or can reasonably be anticipated to cause, because of its toxicity, its toxicity and persistence in the environment, or its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

EPA must make such a determination by rule. Additions would be proposed through publication of a draft rule to provide notice and opportunity for comment on the addition of the chemical to the TRI list. A final rule would be subject to judicial review. A similar process would occur to delete a listed chemical if the Administrator determined there was not sufficient evidence to establish any of the criteria described above for the chemical.

Under EPCRA 313(e), any person may petition the Administrator to add or delete a chemical and the Administrator must take action within 180 days.

The TRI regulations were augmented with respect to persistent bioaccumulative toxic (PBT) chemicals on October 29, 1999, when EPA published a final rule adding some PBT chemicals to the list of toxic chemicals subject to section 313 of EPCRA and section 6607 of the PPA and to lower the reporting thresholds for certain PBT chemicals including mercury, dioxin, and PCBs.

2. How does a chemical, like Metiram, which the toxicity test showed was not causing a problem in animals, make the list?

Based on the 1994 rulemaking record, Metiram is an ethylene bisdithiocarbamate (EBDC) fungicide, and EPA found that sufficient evidence suggested that ethylene bisthiocarbamate fungicides and ethylenethiourea (a common contaminant, metabolite, and degradation product of these fungicides) caused cancer and adverse developmental effects in experimental animals.[5]

In a 2-year diet study, ethylenethiourea caused liver adenomas and carcinomas in mice, and thyroid follicular cell adenomas and carcinomas in mice and rats.[6] A NOAEL of less than or equal to 5 mg/kg has been reported for ethylenethiourea, based on a rat developmental

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[5] 59 FR 1863, 1/12/1994

[6] Support Document for the Health and Ecological Toxicity Review of TRI Expansion Chemicals. U.S. Environmental Protection Agency, Washington, DC (1993), page 95.

toxicity study.[7] Ethylenethiourea caused delayed ossification or hardening of the parietal bone in pups. EPA believed then, as it does now, that there is sufficient evidence for listing metiram on the EPCRA section 313(c) list pursuant to EPCRA section 313(d)(2)(B) based on the carcinogenicity and developmental toxicity data for ethylenethiourea, a metabolite and degradation product of metiram.

3. Please state whether chemicals have been statutorily added to the TRI. Please state whether any of their toxicity profiles are similar to or more benign than that for Metiram.

All of the chemicals that were originally on the TRI list were statutorily added in Committee Print Number 99–169 of the Senate Committee on Environment and Public Works, titled "Toxic Chemicals Subject to Section 313 of the Emergency Planning and Community Right-To-Know Act of 1986."

No chemicals have been added statutorily since the adoption of the law.

With respect to your question regarding whether the toxicity profiles of any of the statutorily added chemicals are similar to or more benign than that for metiram, since there have not been any statutory additions, the Agency does not have anything upon which to base an answer to this question.

4. Please provide a full explanation of the steps EPA must take to ban a PBT. Please state whether there are legal authorities other than TSCA to address PBT chemical risks.

Section 6(a) of TSCA gives EPA the authority to protect against unreasonable risk of injury to health or the environment from chemical substances. If EPA finds that there is a reasonable basis to conclude that the chemical's manufacture, processing, distribution, use or disposal presents an unreasonable risk, EPA may by notice-and-comment rulemaking take action to:

- Prohibit or limit manufacture, processing, or distribution in commerce;
- Prohibit or limit the manufacture, processing, or distribution in commerce of the chemical substance above a specified concentration;
- Require adequate warnings and instructions with respect to use, distribution, or disposal;
- Require manufacturers or processors to make and retain records;
- Prohibit or regulate any manner of commercial use;
- Prohibit or regulate any manner of disposal; and/or

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[7] Id.

- Require manufacturers or processors to give notice of the unreasonable risk of injury, and to recall products if required.

TSCA section 6(a) indicates that EPA should apply the least burdensome means of adequately protecting against the unreasonable risk. In developing a rule under 6(a), TSCA section 6(c) directs EPA to consider and publish a statement with respect to:

1. The effect of the chemical substance being regulated on health and the magnitude of exposure of humans to the substance.
2. The effects of such substance on the environment and the magnitude of exposure of the environment to the substance.
3. The benefits of such substance for various uses and the availability of substitutes for such uses.
4. The reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

Only five ban actions have been taken using this authority since TSCA was enacted, along with the predominantly invalidated Asbestos Ban and Phase-out Rule. The 5th Circuit Court of Appeals decision on the asbestos rule in 1991 had a chilling effect on EPA's use of the TSCA ban authority. To the extent EPA has authority to address chemicals in the various media it regulates, it also has the authority to address PBT chemicals. While the PBT nature of the chemicals may be relevant to a risk finding or Agency priority setting, most EPA authorities do not treat PBTs differently as a class. (Note, though, that PBT-listed chemicals are subject to lower thresholds to trigger Toxics Release Inventory reporting. See 40 C.F.R. § 372.28.) Thus EPA has the broad range of authorities in the environmental statutes available to address PBTs.

The Honorable Joe Barton

1. Please state whether the U.S. EPA was the source for recognition and inclusion of Article 3.3 in the Stockholm Convention concerning new chemicals with POPs characteristics. If not, please explain why this fact was stated in EPA's notice finalizing existing U.S. PBT policy.

As of the date of the issuance of the final PBT policy (November 4, 1999), the negotiation of the Stockholm Convention was ongoing and thus Article 3.3 did not yet exist. As stated in the Federal Register Notice announcing the category for PBT new chemical substances:

> "... development of the TSCA new PBT chemicals policy has occurred in coordination with U.S. national, U.S./Canada binational, and international efforts to identify and control the environmental release of persistent organic pollutants (POPs). The proposed TSCA PBT category has been provided to the Criteria Expert Group (CEG) established at

the first session of the Intergovernmental Negotiating Committee (INC) for an International Legally Binding Instrument for Implementing International Action on Certain Persistent Organic Pollutants, in accordance with the mandate given by the Governing Council of the United Nations Environment Programme (UNEP) in paragraph 9 of its decision 19/13 C (http://irptc.unep.ch/pops/gcpops<INF>-</INF>e.html). The CEG is an open-ended technical working group with a mandate to present to the INC proposals for science-based criteria and a procedure for identifying additional POPs as candidates for future international action. The CEG is to incorporate criteria pertaining to persistence, bioaccumulation, toxicity and exposure in different global regions and should take into account the potential for regional and global transport, including dispersion mechanisms for the atmosphere and the hydrosphere, migratory species, and the need to reflect possible influences of marine transport and tropical climates. At its first meeting, October 26-30, 1998 in Bangkok, the CEG recommended that the INC consider developing a provision encouraging countries and regions to include in their new chemicals schemes elements relating to development and introduction of new chemical POPs. The U.S. described its proposed TSCA new chemicals program policy for the category of PBT new chemicals, and the full text of the October 5, 1998 Federal Register notice was distributed to all delegations as a Conference Room Paper. The CEG's recommendation was accepted at the second meeting of the INC (January 25-29, 1999 in Nairobi) and the INC will consider it further in its deliberations." (64 FR 60194, November 4, 1999).

2. Please state whether EPA's policy for new PBT chemicals followed a foreign policy or was the first of its kind internationally.

EPA's policy for new PBT chemicals was the first of its kind internationally, although certain other governments (e.g, Japan) also recognized PBTs as chemicals of potential concern in their domestic regulatory regimes.

3. Has the existing PBT policy been effective -- in that companies have avoided the development and submission of new chemical PBTs except in cases where the exposures and releases were carefully controlled or avoided entirely?

Through the 1999 Policy Statement on New Chemicals Category for PBTs, EPA adopted specific identification criteria and the associated process that EPA would use in evaluating new chemical substances suspected as being persistent bioaccumulators. The Policy Statement made clear to submitters of new chemical notifications under TSCA section 5 that substances meeting these criteria may need to undergo testing on "P" and "B" endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify "PBT chemical

substances." In addition, the Policy Statement made clear that control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern.

Because EPA is not privy to company business decisions regarding which new chemical substances should be developed, it is not possible for EPA to comment on whether companies have avoided the development and submission of new chemical PBTs since the issuance of this policy statement. During the period from FY01 - FY08, EPA received approximately 290 Pre-Manufacture Notices (PMNs) or Significant New Use Notices (SNUNs) and 370 Low Volume Exemption notifications (LVEs) that were identified by the Agency as "potential" PBTs. There does not appear to be a strong trend over this time period. During its review of "potential" PBT notifications, EPA carefully assesses the chemical substance to ensure that exposures and releases are carefully controlled or avoided entirely. EPA will, if necessary, deny an LVE and/or require binding controls on releases and exposures. For PMNs, EPA will, if necessary, regulate the substance through TSCA section 5(e) Consent Orders/Significant New Use Rules (SNURs), non-5(e) SNURs, or will ban the manufacture of the substance pending the development of upfront testing needed by EPA to conduct a reasoned evaluation of the effects of the substance.

4. On Thursday, February 4, 2010, U.S. EPA deleted its web pages specifically designed to address PBT issues. Apparently, the Agency did this to archive materials that were as old as 2002. However, the "archive" contains materials newer than 2002. Please explain why those materials newer than the archive guidelines were archived and what criteria were used in determining which materials to archive.

We archived the site because the program had been superseded by the enhanced existing chemicals program. However, there are links to active efforts including the PBT Profiler, the Toxics Release Inventory program, and some activities ongoing in EPA's Region 5.

5. EPA's web page states "The PBT program is no longer active." Please explain this statement and whether it means EPA no longer supports its new chemicals PBT policy.

EPA continues to implement its new chemicals policy for PBTs. The PBT program referenced on the EPA website addressed existing chemicals and has been superseded by the enhanced existing chemicals program. This program was and is unrelated to EPA's New Chemicals policy for PBTs.

6. Other than taking down the PBT website, please describe what actions the Obama Administration has taken to demonstrate its support for the Sustainable Futures effort. Please describe what improvements, if any, have occurred on your watch.

The Sustainable Futures Program has been strengthened and enhanced during the Obama Administration. Under Sustainable Futures, EPA offers industry and other stakeholders' powerful computerized methods for the evaluation of chemicals. EPA delivers these tools together with training, technical assistance and regulatory incentives for qualifying New Chemicals developed using the Sustainable Futures tools. In December 2009, EPA launched the Analog Identification Methodology (AIM), a web-based tool to facilitate hazard assessment, promote risk reduction, facilitate informed substitution, foster pollution prevention outcomes, and advance the state-of-the-art in chemical risk assessment. AIM is available at http://aim.epa.gov. AIM has been well received by stakeholders, with over 6,700 AIM assessments conducted in the first four months of public release.

7. Work on implementing the Stockholm POPs Convention has progressed since the Convention entered into force. Despite EPA Administrator Whitman, in May 2001, making the United States a signatory to this Convention by signing the agreement, the United States Senate has not ratified the agreement, and Congress has not approved the necessary statutory changes to TSCA and FIFRA required to fully implement the treaty obligations.

a. Please describe the U.S. government's experience with implementation of the Convention since it entered into force.

The Parties have been actively implementing the Convention, including adding nine POPs to the Treaty last year. While the United States has been able to provide technical assistance and capacity-building to help other countries implement their obligations, as a non-party, we are unable to participate fully in the political or technical aspects of the proceedings as the agreement evolves over time and additional chemicals are added to its scope. Had the United States been a Party, we would have been afforded the opportunity to participate in the decisions to add the nine additional substances. The United States may have also had the opportunity to play a leadership role in determining the direction of these and other decisions taken by the members of the Convention.

b. Please state whether the new chemical listing process has proceeded as the United States anticipated under the treaty as negotiated.

Yes, the listing process has proceeded as anticipated. As stated above, as a non-party, we are unable to participate fully in the political or technical aspects of the proceedings as the agreement evolves over time and additional chemicals are added to its scope. Had the United States been a Party, we would have been afforded the opportunity to participate in the decisions to add the nine additional substances. The United States may have also had the

opportunity to play a leadership role in determining the direction of these and other decisions taken by the members of the Convention.

c. Please state whether the treaty as implemented has changed in any respect from the treaty as negotiated by the United States.

The treaty has been amended to include a new Annex G on Arbitration and Conciliation Procedures for Settlement of Disputes, and to include nine new POPs in the Convention. These chemicals are Pentachlorobenzene, C-Octabromobiphenyl ether components, C-Pentabromobiphenyl ether components, Alpha HCH, Beta HCH, Gamma HCH, Chlordecone, Hexabromobiphenyl, and PFOS.

8. EPA established a PMN policy with respect to new PBT chemicals in 1999.

a. Please explain the Agency's experience implementing that policy.

Through the 1999 Policy Statement on New Chemicals Category for PBTs, EPA adopted specific identification criteria and the associated process that EPA would use in evaluating new chemical substances suspected as being persistent bioaccumulators. The Policy Statement made clear to submitters of new chemical notifications under TSCA section 5 that substances meeting these criteria may need to undergo testing on "P" and "B" endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify "PBT chemical substances." In addition, the Policy Statement made clear that control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern.

During its review of "potential" PBT notifications, EPA carefully assesses the chemical substance to ensure that exposures and releases are carefully controlled or avoided entirely. EPA will, if necessary, deny an LVE and/or require binding controls on releases and exposures. For PMNs, EPA will, if necessary, regulate the substance through TSCA section 5(e) Consent Orders/Significant New Use Rules (SNURs), non-5(e) SNURs, or will ban the manufacture of the substance pending the development of upfront testing needed by EPA to conduct a reasoned evaluation of the effects of the substance.

During the period from FY01 - FY08, EPA received approximately 291 Pre-Manufacture Notices (PMNs) or Significant New Use Notices (SNUNs) and 369 Low Volume Exemption notifications (LVEs) that were identified by the Agency as "potential" PBTs. All of these were regulated/restricted by EPA in some fashion or were withdrawn by the submitter during the review period. LVEs that were not withdrawn were either denied by EPA or were bound to the terms of the exemption notice (i.e., strict control on releases and exposures). All of the PMNs/SNUNs that were not withdrawn were regulated with 5(e) Consent Orders/SNURS, non-5(e) Consent Orders, or were banned pending upfront testing.

Of the section 5 notices submitted between FY01 thru FY08, we identified the chemicals in 369 Low Volume Exemptions and 291 PMNs/SNUNs as potential PBTs.

b. Please state the number of new PBT substances that have been introduced into commerce since 1999.

The Agency did not begin tracking PBTs in the new chemicals program until Fiscal Year 2001. Starting in Fiscal Year 2001, about 6% of all new chemical notices have been determined to be PBTs, for a total of 680 through 2008. There does not seem to be a discernible trend that we can identify, but the range is from a low of 56 in 2008 to a high of 109 in 2002.

c. Please describe the risk management measures, if any, the Agency required for those substances.

In our new chemicals program, it is our policy to ban Pre-Manufacture Notice chemicals that have a persistence >6 months and bioaccumulation >5000 pending upfront testing, and, for chemicals with persistence >2 months and bioaccumulation >1000, to regulate under a TSCA section 5(e) order to control exposures and releases, and to require testing.

Based on section 5 notices, between FY01 thru FY08 we identified the chemicals in 369 LVEs and 291 PMNs/SNUNs as potential PBTs. All of these were regulated/restricted by EPA in some fashion or were withdrawn by the submitter during the review period. LVEs that were not withdrawn were either denied by EPA or were bound to the terms of the exemption notice (i.e., strict control on releases and exposures). The PMNs/SNUNs that were not withdrawn were regulated with 5(e) Consent Orders/SNURS, non-5(e) Consent Orders, or were banned pending upfront testing.

d. Please state whether the PMN policies have been effective in minimizing or eliminating risks to human health or the environment, and if so, how.

EPA believes the implementation of the 1999 Policy Statement on New Chemicals Category for PBTs has led to the identification and risk management of PBT chemicals within the New Chemicals program. Through the Policy Statement, EPA adopted specific identification criteria and the associated process that EPA would use in evaluating new chemical substances suspected as being persistent bioaccumulators. The Policy Statement made clear to submitters of new chemical notifications under TSCA section 5 that substances meeting these criteria may need to undergo testing on "P" and "B" endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify "PBT chemical substances." In addition, the Policy Statement made clear that control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern.

Starting in Fiscal Year 2001, about 6% of all New Chemical notices have been determined to be PBTs, for a total of 680 through 2008. Based on section 5 notices, between FY01 thru FY08 we identified the chemicals in 369 LVEs and 291 PMNs/SNUNs as potential PBTs. All of these were regulated/restricted by EPA in some fashion or were withdrawn by the submitter during the review period. LVEs that were not withdrawn were either denied by EPA or were bound to the terms of the exemption notice (i.e., strict control on releases and exposures). The PMNs/SNUNs that were not withdrawn were regulated with 5(e) Consent Orders/SNURS, non-5(e) Consent Orders, or were banned pending upfront testing.

9. Please describe any steps the Agency is taking to address the findings of the 2008 Society of Environmental Toxicology and Chemistry's Pellston Workshop on PBT characteristics. Please also describe how the Agency is incorporating the developing science and better identifying PBT substances identified by that Pellston workshop, the goal of which was to improve the process of identification and evaluation of chemicals against the PBT criteria.

The Pellston Workshop are Society of Environmental Toxicology and Chemistry (SETAC) sponsored meetings whose purpose is to evaluate current and prospective environmental issues. At the 2008 Pellston Workshop, the principal objective was to develop consensus guidance on how to evaluate chemicals using scientific information such as experimental data, monitoring data, and computer models to determine if they fulfill PBT criteria (Kleèka et al., *IEA&M* 2009, 5:535-538). The workshop results have been presented in a series of technical papers in the October 2009 issue of the journal *Integrated Environmental Assessment and Management* (IEA&M).

Efforts to improve our program in this area include employing a dedicated team of senior scientists to perform predictive calculations for industrial chemicals; updating our bioaccumulation model to include an absorption, distribution, metabolism and excretion (ADME) component which predicts the metabolism of chemicals; and incorporating environmental compartment-specific half-lives into the evaluation of chemical persistence.

10. Please describe the impact of EPA's New Chemicals PBT Policy on the number of new PBT chemicals. Of the new PBT chemicals of which EPA has been notified, please state the general trend for release of these chemicals into the environment?

EPA did not begin tracking PBTs in its new chemicals program until Fiscal Year 2001. Starting in FY2001, about 6% of all new chemical notices have been determined to be PBTs, for a total of 680 through 2008. There does not seem to be a discernible trend that we can identify, but the range is from a low of 56 in 2008 to a high of 109 in 2002. Based on section 5 notices, between FY01 thru FY08 we identified the chemicals in 369 LVEs and 291 PMNs/SNUNs as potential PBTs. All of these were regulated/restricted by EPA in some fashion or were withdrawn by the

submitter during the review period. LVEs that were not withdrawn were either denied by EPA or were bound to the terms of the exemption notice (i.e., strict control on releases and exposures). The PMNs/SNUNs that were not withdrawn were regulated with 5(e) Consent Orders/SNURS, non-5(e) Consent Orders, or were banned pending upfront testing.

11. Your testimony references EPA's PBT Profiler tool, which I have been told was designed largely for industry's use in designing safer/greener new chemicals. Please generally identify the primary users of this tool and describe the benefits derived from that use.

The PBT Profiler was designed to be used by public stakeholders with a wide variety of technical skills and expertise and was jointly developed by industry, Environmental Defense, and EPA. It was released to the public in 2002.

The PBT Profiler interprets the results for non scientists so that a broader array of stakeholders can assess PBT characteristics. The user base of the PBT Profiler is wide and diverse. The methodology is used by industry, the public, NGOs, academic and research institutions, State environmental agencies, and other parts of the U.S. Federal Government, among others. Stakeholders have conducted over 200,000 chemical specific PBT screening studies using the PBT Profiler.

The PBT Profiler offers users many benefits. The tool can be used to estimate PBT characteristics for new chemicals and can be used to compare and contrast existing chemicals for PBT characteristics. This can help drive informed chemical substitution and identify pollution prevention and risk reduction opportunities. As examples, Bayer Chemical Company used the PBT Profiler to compare and contrast alternatives at research and development phase for a new chemical. The Dutch Government used the Profiler to evaluate 50 chemicals detected in harbor sediments. The Federal Aviation Administration used the Profiler to evaluate safety of chemicals used in aircraft components. SC Johnson evaluated chemicals in their supply chain for PBT characteristics. FMC Corporation evaluated 50 chemicals for PBT traits.

12. In responding to a question from Representative Whitfield on the difference in legal standards between TSCA chemicals and FIFRA pesticides, you mentioned the pesticide standard of "reasonable certainty of no harm". Please state whether there are distinct differences between routes of exposure for pesticides, governed under FIFRA, versus other chemicals which could be subject to TSCA.

Yes, "reasonable certainty of no harm" is the standard for issuing pesticides tolerances from the Food Quality Protection Act and the "no significant adverse effects" language is from TSCA. The potential routes of exposure assessed under FIFRA and TSCA are the same; dermal, inhalation,

AL 12-001-8222

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510-6175

October 25, 2012

Jim Jones
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Dear Acting Assistant Administrator Jones:

Thank you for appearing before the Committee on Environment and Public Works on July 24, 2012, at the hearing entitled, "Oversight of EPA Authorities and Actions to Control Exposures to Toxic Chemicals." We appreciate your testimony and we know that your input will prove valuable as we continue our work on this important topic.

Enclosed are questions for you that have been submitted by Senator Boxer for the hearing record. Please submit your answers to these questions by COB November 8, 2012, to the attention of Mara Stark-Alcalá, Senate Committee on Environment and Public Works, 410 Dirksen Senate Office Building, Washington, DC 20510. In addition, please provide the Committee with a copy of your answers via electronic mail to Mara_Stark-Alcala@epw.senate.gov. To facilitate the publication of the record, please reproduce the questions with your responses.

Again, thank you for your assistance. Please contact Grant Cope of the Majority Staff at (202) 224-8832, or Dimitri Karakitos of the Minority Staff at (202) 224-6176 with any questions you may have. We look forward to reviewing your answers.

Sincerely,

Barbara Boxer
Chairman

James M. Inhofe
Ranking Member

Environment and Public Works Committee Hearing
July 24, 2012
Follow-Up Questions for Written Submission

Questions for Jones

Questions from:

Senator Barbara Boxer

1. A study by researchers at the University of California at San Francisco detected certain PBDEs, PCBs, phthalates, pesticides, perchlorate and other chemicals in the blood of 99 to 100% of pregnant women that they tested.

    a. Can pre-term exposure to chemicals increase the risk of harmful health effects?

    b. If so, please describe the range of such harmful health effects that can occur as a result of such exposures, including any impacts that may harm reproduction or development in later generations of people?

2. One study published last year by researchers from the California Department of Toxic Substances Control and the University of California at San Francisco studied blood samples from pregnant women in California -- and found that they generally had higher levels of PBDEs than other women in the United States, as well as Europe and Asia, and that the women also had lower levels of hormones produced by the thyroid.

    a. What impact does the thyroid have on ensuring the healthy development of infants and children?

    b. What impact can lower levels of thyroid hormones have on a women's ability to become pregnant and to carry that pregnancy to term?

    c. How can the differing levels of PBDE in the blood of pregnant women help to inform risk assessment and risk management decisions for these?

3. In 2012, EPA issued an Existing Chemicals Program Strategy to identify chemicals for review based on various factors, including a chemical's potential for exposure, persistence, and bioaccumulation. The Agency issued Work Plans to begin assessing 83 chemicals in 2012. The EPA has also issued work plans to assess 18 more chemicals, including 3 flame retardants – beginning in 2013. In your testimony, you state that EPA is currently developing a strategy, scheduled for completion by the end of this year, to address flame retardant chemicals.

    a. Please describe whether TSCA provides EPA with the necessary tools to fully assess the risks of flame retardant chemicals?

    b. Please describe whether TSCA provides EPA with the necessary tools to fully address the risks posed by such chemicals through implementing and enforcing risk management decisions?

4. Please describe how the existing TSCA assessment process fails to identify chemical hazards and how TSCA reform will allow EPA to identify such persistent, bioaccumulative and toxic

chemicals before they commercialized and allow EPA to take effective action after such chemicals are in commerce, when needed.

5. The National Academy of Sciences (NAS) published "Science and Decisions: *Advancing Risk* Assessment" in 2009, which recommended several actions that EPA should take to modernize its approach to assessing chemicals' risks to human health, including for infants and children. For each of the recommendations below, list and describe the specific activities that EPA has on-going or plans to take, including timelines for completing such actions, in order to fully implement the recommendations:

    a. NAS recommendations for EPA to modernize its methodology for assessing chemical risks, including:
        i. Revising its default assumptions on the risks posed by chemicals;
        ii. Developing explicit defaults about chemical risks, including for cancer and some non-cancer health effects, rather than continuing to use more informal approaches for approximating such risks (such as using "implied" defaults); and,
        iii. Over a two-to-five year period, developing clear criteria on the information needed to justify the use of alternative risk assumptions, rather than explicitly-stated risk defaults for chemicals.

    b. NAS recommendations for EPA to modernize its methodology for assessing non-cancer health effects, including:
        i. Over the short-term, using contemporary methods ("probabilistic" methods) for determining health effects from low-dose exposures to chemicals; considering factors such as vulnerable populations, background exposures to chemicals, the impact of existing disease burdens in people, as well as developing defaults risk estimates and guidance on the consideration of such factors; and using information and estimates of human susceptibility to cancer; and
        ii. Over the long-term, better understanding the occurrence of human vulnerability and susceptibility to chemicals by expanding the Agency's research on such issues, and better understanding how multiple chemical exposures can add together to harm human health by researching the interaction of chemicals that can have the same type of toxic impact, but have potentially different ways of causing such harm.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 3 1 2013

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Barbara Boxer
Chairman
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510-6175

Dear Chairman Boxer:

Thank you for the opportunity to respond to the questions for the record following the July 24, 2012, hearing on "Oversight of EPA Authorities and Actions to Control Exposures to Toxic Chemicals." The attached document has responses to the questions. I hope that this information is useful to you and the members of the committee.

If you have any further questions, please contact me or your staff may call Sven-Erik Kaiser in my office at (202) 566-2753.

Sincerely,

Arvin Ganesan
Associate Administrator

Attachment

Senate Environment and Public Works Committee
Hearing on "Oversight of EPA Authorities and Actions to Control Exposures to Toxic Chemicals"
Questions for the Record
Jim Jones, Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
July 24, 2012

Senator Barbara Boxer, Chairman

Boxer 1. A study by researchers at the University of California at San Francisco detected certain PBDEs, PCBs, phthalates, pesticides, perchlorate and other chemicals in the blood of 99 to 100% of pregnant women that they tested.

1a. Can pre-term exposure to chemicals increase the risk of harmful health effects?

Answer: As a general matter, the mere presence of chemicals in the blood does not necessarily indicate harmful effects. Observational studies with human subjects and laboratory studies with animals can be used to study health effects from exposure to chemicals. Some laboratory studies with animals have shown that pre-term exposure to some chemicals can cause harmful health effects to the offspring if the exposure or dose to the pregnant animal is high enough, and occurs during a critical period of fetal development.[1] Observational studies with human subjects can also demonstrate health effects from exposure to chemicals.

1b. If so, please describe the range of such harmful health effects that can occur as a result of such exposures, including any impacts that may harm reproduction or development in later generations of people?

Answer: Both the effects of exposure and the likelihood (risk) that people might develop that effect vary significantly by chemical (mode and mechanism of action), the dose received, and the timing of exposure. Laboratory animal and non-animal studies to understand reproductive and developmental effects in later generations of people is currently an active research area, but uncertainties remain regarding such studies' relevance to humans, at the doses where effects are seen in test systems. The EPA's Guidelines for Developmental Toxicity Risk Assessment[2] provides a description of the endpoints commonly measured in laboratory animal studies and human epidemiological studies. The EPA also uses multigenerational reproductive toxicity assays in laboratory animals to assess potential impacts on future generations.

Boxer 2. One study published last year by researchers from the California Department of Toxic Substances Control and the University of California at San Francisco studied blood samples from pregnant women in California – and found that they generally had higher levels of PBDEs than other women in the United States, as well as Europe and Asia, and that the women also had lower levels of hormones produced by the thyroid.

2a. What impact does the thyroid have on ensuring the healthy development of infants and children?

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[1] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3114826/pdf/ehp-119-878.pdf
[2] http://www.epa.gov/raf/publications/pdfs/DEVTOX.PDF

Answer: Please note that the observation of the presence of a chemical in human blood samples coupled with observations of altered hormone levels or other outcomes does not establish causation. The thyroid gland and thyroid hormones play an important role in the body throughout life. Every cell in the body relies on thyroid hormones to work properly. Important functions mediated by thyroid hormones include, but are not limited to: metabolism; muscle and joint function; cardio vascular fitness; digestions; bone health; hormone balance; and brain function. In infants and children, proper levels of thyroid hormone influence these functions as well as the normal progression of development. A known consequence of abnormal thyroid hormone levels during development is abnormal neurological development. For example, extremely low dietary iodine levels over a significant amount of time, most commonly in parts of the world with iodine-deficient diets, results in lowered production of thyroid hormones and this has resulted in neonatal hypothyroidism with severe physical and mental retardation in children. Note that there is a range of normal variability in hormone levels; the presence and severity of adverse effects depends on the magnitude of hormone level alteration. With less extreme hypothyroidism and poor iodide intake, the National Academy of Sciences has stated[3]:

> "Newborn infants who have hypothyroidism may have other abnormalities, including lethargy, poor muscle tone, poor feeding, constipation, and persistent jaundice, if not at birth then thereafter. The changes are similar to those which occur in older children and adults who have hypothyroidism, and, in contrast with the neurologic abnormalities, they are reversible with adequate T4 [thyroid hormone] treatment."
>
> "Pregnant women who have subclinical hypothyroidism or overt hypothyroidism and are inadequately treated or not treated at all have an increased risk of fetal loss. The infants of those mothers who do not miscarry have normal thyroid function at birth and thereafter, but their neurodevelopment may be slightly impaired."

2b. What impact can lower levels of thyroid hormones have on a woman's ability to become pregnant and to carry that pregnancy to term?

Answer: In adult females, if altered sufficiently, thyroid hormone levels can influence a woman's ability to become pregnant and to maintain that pregnancy. Important functions relevant to reproduction that are mediated by thyroid hormones include, but are not limited to: sexual function and libido, hormone balance, and ovulation. With regard to carrying pregnancy to term, the National Academy of Sciences stated[4]: "Pregnant women who have subclinical hypothyroidism or overt hypothyroidism and are inadequately treated or not treated at all have an increased risk of fetal loss."

2c. How can the differing levels of PBDE in the blood of pregnant women help to inform risk assessment and risk management decisions?

Answer: Biomonitoring studies provide valuable information on exposure and are most beneficial when used with an understanding of a chemical's toxicity. Blood levels (or levels in urine or a tissue such as fat) of a specific chemical reflect exposure from ingestion, inhalation and other exposure

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[3] From: Chapter 2, "The Thyroid and Disruption of Thyroid Function in Humans" in Health Implications of Perchlorate Ingestion (2005).

[4] *Ibid.*

pathways. With an understanding of how a chemical is distributed and transformed in the body, biomonitoring data can be used in conjunction with toxicity data to inform the potential risk from exposure to that specific chemical. Thus, knowledge of the levels of a chemical in people's blood can have a significant impact on risk assessment. Further, when coupled with knowledge of the sources and pathways of exposure, biomonitoring can be of value in informing decisions on risk reduction through reduction in specific exposures.

Boxer 3. In 2012, EPA issued an Existing Chemicals Program Strategy to identify chemicals for review based on various factors, including a chemical's potential for exposure, persistence, and bioaccumulation. The Agency issued Work Plans to begin assessing 83 chemicals in 2012. The EPA has also issued work plans to assess 18 more chemicals, including 3 flame retardants – beginning in 2013. In your testimony, you state that EPA is currently developing a strategy, scheduled for completion by the end of this year, to address flame retardant chemicals.

3a. Please describe whether TSCA provides EPA with the necessary tools to fully assess the risks of flame retardant chemicals?

Answer: When the Toxic Substances Control Act (TSCA) was enacted in 1976, it represented an important step forward in addressing the risks from industrial chemicals by granting the EPA jurisdiction over chemicals produced, used, and imported in the United States. Today, TSCA is the only major environmental statute that has not been reauthorized. Unlike the laws applicable to drugs and pesticides, TSCA does not have a mandatory program where the EPA must conduct a review to determine the safety of the more than 84,000 existing chemicals. In addition, TSCA places challenging legal and procedural requirements on the EPA before the agency can request the generation and submission of any health and environmental effects data on existing chemicals.

The EPA has developed a more effective program under TSCA to review new chemicals before introduction to the marketplace. The EPA uses professional judgment and information on similar chemicals to evaluate existing chemicals.

3b. Please describe whether TSCA provides EPA with the necessary tools to fully address the risks posed by such chemicals through implementing and enforcing risk management decisions?

Answer: When the EPA determines that a chemical poses a significant health concern, taking action under TSCA to limit or ban a chemical is challenging. For example, in 1989, after years of study and nearly unanimous scientific opinion, the EPA issued a rule phasing out most uses of the cancer causing substance asbestos. Yet, a federal court overturned most of this action because the EPA failed to clear the hurdles imposed under TSCA before existing chemicals can be controlled.

The agency is committed to utilizing the current statute to the fullest extent possible and taking risk management actions to address chemicals that may pose a concern— including brominated flame retardants (BFRs). For example, in late 2009, the EPA released an Action Plan on polybrominated diphenyl ethers (PBDEs), a group of BFRs, that highlighted concerns and specific steps the agency is taking to address those concerns.[5] In April 2012, the EPA proposed a rule requiring additional testing of

[5]U.S. EPA, Polybrominated Diphenyl Ethers (PBDEs) Action Plan Summary (2009), http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/pbdes_ap_2009_1230_final.pdf.

these chemicals and the requirement that any new uses of these chemicals be submitted to the agency for review.[6] The EPA is also working with the industry and a wide range of stakeholders, under our Design for the Environment Program, on assessing alternatives to some of these chemicals to inform choices of alternatives.[7]

On March 27, 2013, the EPA made public a list of 23 chemicals for assessment beginning in 2013. The EPA will conduct full risk assessments on four flame retardant chemicals. The four flame retardant chemicals are 2-Ethylhexyl ester 2,3,4,5- tetrabromobenzoate (TBB); 1,2- Ethylhexyl 3,4,5,6-tetrabromo-benzenedicarboxylate, or (2-ethylhexyl)-3,4,5,6 tetrabromophthalate (TBPH); Tris(2-chloroethyl) phosphate (TCEP); and Hexabromocyclododecane (HBCD). The EPA will utilize a new structure based approach, grouping chemicals with similar characteristics together with the chemicals targeted for full assessment under the TSCA Workplan. The review of similar chemicals in related groupings, and the environmental fate investigations for other chemicals, complements the risk assessments by focusing the identification of data needs on chemical classes with members that rank high for specific criteria in the Work Plan methodology, but lack sufficient data to conduct risk assessment. The EPA will use the information from these assessments to better understand the other chemicals in the group, which currently lack sufficient data for a full risk assessment. The agency will also begin environmental fate investigations of eight additional flame retardant chemicals that rank high for persistence, bioaccumulation and/or exposure potential, but for which there are not adequate data to conduct risk assessments.

Boxer 4. Please describe how the existing TSCA assessment process fails to identify chemical hazards and how TSCA reform will allow EPA to identify such persistent, bioaccumulative and toxic chemicals before they commercialized and allow EPA to take effective action after such chemicals are in commerce, when needed.

Answer: For new chemicals, TSCA requires that they must go through a pre-manufacture review at the EPA 90 days prior to commencing manufacture. The required notification provides the EPA with the opportunity to evaluate the chemical and, if necessary, to impose restrictions on activities that give rise to human health or environmental risk or exposure concerns before they occur.

As stated in the response to question 3 above, TSCA does not have a mandatory program where the EPA must conduct a review to determine the safety of existing chemicals. The statute places challenging legal and procedural requirements on the EPA before the agency can request the generation and submission of any health and environmental effects data on existing chemicals. As the EPA explained in its announcement of Essential Principles for Reform of Chemicals Management Legislation,[8] all chemicals should be reviewed against a science based safety standard that reflects risk based criteria protective of human health and the environment, including the health of children and other vulnerable populations, and, manufacturers should be required to provide the EPA with the necessary information to conclude that new and existing chemicals are safe. When manufacturers do not submit sufficient information, the EPA should have the necessary authority and tools to quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals. The EPA

[6] U.S. EPA, Significant New Use and Test Rules: Certain Polybrominated Diphenylethers, 2012, http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2010-1039-0001.

[7] U.S. EPA, http://www.epa.gov/dfe/alternative_assessments.html.

[8] http://www.epa.gov/oppt/existingchemicals/pubs/principles.html

should also have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations.

Boxer 5. The National Academy of Sciences (NAS) published "Science and Decisions: Advancing Risk Assessment" in 2009, which recommended several actions that EPA should take to modernize its approach to assessing chemicals' risks to human health, including for infants and children. For each of the recommendations below, list and describe the specific activities that EPA has ongoing or plans to take, including timelines for completing such actions, in order to fully implement the recommendations.

5a. NAS recommendations for EPA to modernize its methodology for assessing chemical risks, including:

i. Revising its default assumptions on the risks posed by chemicals;
ii. Developing explicit defaults about chemical risks, including for cancer and some non-cancer health effects, rather than continuing to use more informal approaches for approximating such risks (such as using "implied" defaults); and
iii. Over a two-to-five year period, developing clear criteria on the information needed to justify the use of alternative risk assumptions, rather than explicitly-stated risk defaults for chemicals.

Answer: EPA's Science and Technology Policy Council (STPC)[9] recently established the NRC Risk Assessment Reports Workgroup to address the NRC recommendations from four recent NRC reports: "Science and Decisions: Advancing Risk Assessment", "Phthalates and Cumulative Risk Assessment", "Toxicity Testing in the 21st Century", and "Exposure Science in the 21st Century: A Vision and A Strategy". This workgroup is charged with developing options and recommendations to the STPC and the EPA Science Advisor on additional steps that could be taken by the Agency to address recommendations from the relevant NRC reports, and with reviewing communications materials and summaries regarding the progress to date on incorporating the NRC recommendations into the EPA activities, including those to be sent to the SEPW.

The EPA policies regarding the current use of defaults are described in several agency documents. For example, the "Guidelines for Carcinogen Risk Assessment"[10] explain that the assessor must critically analyze the available relevant information before using a default to address uncertainty in the absence of critical information.

The EPA continues to evaluate the National Research Council (NRC) recommendations on the use of defaults and will develop additional guidance as necessary to incorporate new methods into agency practice. Concurrently, the EPA released the draft "Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation"[11] in 2011. This document outlines approaches for using data to develop factors to compensate for uncertainties in extrapolating from animal toxicity studies to humans and to address human variability. The external review draft is publically available and is expected to be released in final form in 2013.

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[9] U.S. EPA, Science and Technology Policy Council, http://www.epa.gov/stpc/.
[10] U.S. EPA, Guidelines for Carcinogen Risk Assessment (2005), U.S. Environmental Protection Agency, Washington, DC, EPA/630/P-03/001F, 2005, http://www.epa.gov/cancerguidelines.
[11] U.S. EPA, External Review Draft of the Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation, U.S. Environmental Protection Agency, Washington, DC, EPA/100/J-11/001, 2011, http://www.epa.gov/osa/raf/ddefreview.htm.

The NRC highlighted an issue they termed "missing defaults", i.e., understanding risk only for those chemicals with a robust toxicity database. Through its Chemical Safety for Sustainability (CSS)[12] and Human Health Risk Assessment (HHRA)[13] research programs, the EPA is developing new methods and databases to assess chemicals with limited traditional toxicity data. Consistent with science and decisions as well as the recommendations from the 2007 NRC report, "Toxicity Testing in the 21st Century: A Vision and A Strategy," the ultimate goal is to compile all available chemical information and data, including chemical screening data generated from innovative chemical evaluation methods, into one accessible online application that interested users can access and select chemicals and data of interest in order to make informed decisions about chemical risks. CSS is building these accessible online applications using data generated from these innovative chemical screening methods that can be used to understand how chemicals perturb pathways that potentially lead to adverse effects. This will help reduce uncertainty related to species specificity, lifestage susceptibility, and dose response characterization, and allow the EPA to focus resources on those chemicals and endpoints of highest concern. The methods and databases developed through these efforts will be made publically available.

Likewise, through the HHRA research program, building from and expanding upon approaches used to develop Integrated Science Assessments, the EPA is addressing the NRC recommendations and applying new approaches to Integrated Risk Information System (IRIS) assessments, including increased transparency regarding alternative risk methodologies.

One example of a product resulting from these efforts is the Aggregated Computational Toxicology Online Resource,[14] a web based application that provides public access to more than 1,000 public sources of information on more than 500,000 environmental chemicals, 30 years worth of animal toxicity testing data, innovative chemical screening (called high-throughput data) from over 1,000 chemicals tested in more than 650 different tests, chemical structure information for 8,000 chemicals and chemical exposure predictions. Additionally, the EPA and several other federal agencies initiated the Toxicity Testing in the 21st Century (Tox21) collaboration,[15] which will use robotics technology to screen 8,000 chemicals for potential toxicity, and will continue to improve models for predicting both hazard (ToxCastDB[16]) and exposure (ExpoCastDB[17]). These projects will provide screening level data and methods on thousands of chemicals that do not have robust traditional toxicity and exposure datasets, which will inform the risk assessment of these chemicals.

5b. NAS recommendations for EPA to modernize its methodology for assessing non-cancer health effects, including:

i. Over the short-term, using contemporary methods ("probabilistic methods) for determining health effects from low-dose exposure to chemicals; considering factors such as vulnerable populations, background exposures to chemicals, the impact of existing disease burdens in people, as well as developing default risk estimates and guidance on the consideration of such factors; and using information and estimates of human susceptibility to cancer; and
ii. Over the long-term, better understanding the occurrence of human vulnerability and susceptibility to chemicals by expanding the Agency's research on such issues, and better

[12] U.S. EPA, Chemical Safety for Sustainability, http://www.epa.gov/research/progressreport/chemical.htm.
[13] U.S. EPA, Human Health Risk Assessment, http://www.epa.gov/research/progressreport/humanhealth.htm.
[14] U.S. EPA, Aggregated Computational Toxicology Online Resource, http://www.epa.gov/ncct/actor/.
[15] NIH, Toxicology in the 21st Century, http://www.ncats.nih.gov/research/reengineering/tox21/tox21.html.
[16] U.S. EPA, ToxCast Database, http://www.epa.gov/ncct/toxcast.
[17] U.S. EPA, ExpoCastDB: Exposure Forecaster Database. http://www.epa.gov/ncct/expocast/.

understanding how multiple chemical exposures can add together to harm human health by researching the interaction of chemicals that can have the same type of toxic impact, but have potentially different ways of causing such harm.

Answer: The EPA recognizes that addressing background in dose-response and exposure assessment is a complex issue. When data are available, the agency considers both background exposures (in the environment and within the body) in dose response analysis, and background incidence of disease processes in characterizing susceptibility and variability in human response. In Integrated Risk Information System (IRIS) assessments, multiple sources of background data are discussed and considered when they occur: endogenous background (produced within the body), anthropogenic (man-made) and natural background as it pertains to dose-response, and background exposure to essential nutrients/trace metals. In addition, the Integrated Science Assessments of ozone[18], carbon monoxide[19], and particulate matter[20] consider background disease processes such as asthma in evaluating susceptibility and human vulnerability.

The EPA is also developing a cumulative health assessment for six phthalates that cause a common health endpoint (male developmental/reproductive outcomes): butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), diisononyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), and dipentyl phthalate (DPP). This cumulative assessment may serve as a future framework for evaluating other groups of compounds that cause similar adverse outcomes.

The EPA's Risk Assessment Forum, under the oversight of the agency's Science and Technology Policy Council, has been charged with developing Guidelines for Cumulative Risk Assessment (CRA). Previously, the forum developed a "Framework for Cumulative Risk Assessment[21] published in 2003. Since then, the EPA conducted three workshops and prepared several white papers. Additionally, a series of case studies focusing on CRA issues and methods was developed for internal use to inform development of the CRA Guidelines. Draft CRA Guidelines for internal review are anticipated in 2013, followed by external peer review in 2014.

Probabilistic risk analysis (PRA) plays an increasingly important role in agency risk assessments since the 1997 EPA publication, "Guiding Principles for Monte-Carlo Analysis."[22] It was also a major focus in an associated review of the EPA practices by the agency's Science Advisory Board in September 2006.[23] The importance of using PRA is reflected by a number of advisory scientific panels and is an integral part of the EPA guidelines. The Risk Assessment Forum is developing two white papers that examine the use of probabilistic approaches in agency risk assessment and risk management. The papers provide a general overview of the value of probabilistic analyses and similar or related methods, and

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[18] U.S. EPA, Integrated Science Assessment of Ozone and Related Photochemical Oxidants (Second External Review Draft), U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-10/076B, 2011, http://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=242490.

[19] U.S. EPA Integrated Science Assessment for Carbon Monoxide, U.S. Environmental Protection Agency, Research Triangle Park, NC, EPA/600/R-09/019F, 2010, http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=218686.

[20] U.S. EPA, Integrated Science Assessment for Particulate Matter, U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-08/139F, 2009, http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546.

[21] U.S. EPA. Framework for Cumulative Risk Assessment. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington Office, Washington, DC, EPA/600/P-02/001F, 2003, http://www.epa.gov/raf/publications/framework-cra.htm.

[22] U.S. EPA. Guiding Principles for Monte Carlo Analysis. U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, DC, EPA/630/R-97/001, 1997, http://www.epa.gov/raf/publications/guiding-monte-carlo-analysis.htm.

[23] U.S. EPA SAB, Consultation on Enhancing Risk Assessment Practices and Updating EPA's Exposure Guidelines, February 28, 2007, http://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/55E1B2C78C6085EB8525729C00573A3E/$File/sab-07-003.pdf.

case studies of current applications across the agency are also included. The external review draft is publically available[24] and expected to be released in final form in 2013.

[24] U.S. EPA, Two External Review Drafts on Probabilistic Risk Assessment, http://www.epa.gov/raf/prawhitepaper/index.htm

AL 11-001-3200

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510–6175

August 3, 2011

The Honorable Steve Owens
Assistant Administrator
Office of Pollution, Prevention and Toxics
US Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20009

Dear Assistant Administrator Owens:

Thank you for appearing before the Committee on Environment and Public Works on February 3, 2011 at a hearing entitled, "Assessing the Effectiveness of US Chemical Safety Laws." We appreciate your testimony, and we know that your input will prove valuable as we continue our work on this important topic.

Enclosed are questions that have been submitted by Senators Boxer and Inhofe for the hearing record. Please submit your answers to these questions by COB August 18, 2011 to the attention of Katie Lee, Senate Committee on Environment and Public Works, 410 Dirksen Senate Office Building, Washington, DC 20510. In addition, please provide the Committee with a copy of your answers via electronic mail to Katie_Lee@epw.senate.gov. To facilitate the publication of the record, please reproduce the questions with your responses.

Again, thank you for your assistance. Please contact Grant Cope of the Majority Staff at (202) 224-8832, or Dimitri Karakitsos of the Minority Staff at (202) 224-6176 with any questions you may have. We look forward to reviewing your answers.

Sincerely,

Barbara Boxer
Chairman

James M. Inhofe
Ranking Member

Environment and Public Works Subcommittee Hearing
February 3, 2011
Follow-Up Questions for Written Submission

Questions for Assistant Administrator Owens

Questions from:

Senator Barbara Boxer

1. In 2009, EPA initiated a chemical action plan for existing chemicals. Could you please describe the reasons for these plans, benefits of this type of action and any difficulties that the Agency has experienced when developing and implementing the plans? Please also describe:
   A. How the creation of these plans and the generation of information resulting from these plans can be expedited,

   B. Any gaps in information needed to protect public health that may remain following the completion of these plans, and

   C. Whether this type of information, and any additional information, should generally be provided for other chemicals, including new chemicals if the Toxic Substances Control Act is modified during re-authorization.

2. In 2008, EPA issued a safeguard to address the threats to human health, including children's health, from lead chips and dust during and following renovation and repair work. Please describe the expected benefits of the Agency's implementation of the Lead, Repair and Renovation safeguards, how implementation is progressing, and the steps that the Agency has taken to ease implementation for small businesses.

Senator James M. Inhofe

1. Please describe your view of the "new chemicals program." Does the program allow companies to send dangerous chemicals into the stream of commerce without any controls or restrictions?

2. Could you describe what information is required to be submitted under the new chemicals program when a company submits a pre-manufacture notice? After this information is submitted to the agency, does EPA analyze it or conduct any sort of assessment? If so, after an assessment is conducted, does EPA have the ability to prohibit or limit manufacture of the substance or ask the company to develop and submit additional data?

3. How is EPA striking the proper balance between protecting confidential business information and providing the public with information they need?

A. With six IRIS risk assessments currently being delayed and reviewed due to concerns over the lack of "scientific integrity," what steps has the EPA taken to ensure that chemicals are properly reviewed using the best available science to get accurate and unbiased results?

4. Many advocates of TSCA reform, including EPA, argue regularly that the current TSCA law does not "provide the tools" necessary "to adequately protect human health and the environment." Recently, EPA has drafted an "Inventory Update Reporting" rule to expand industries reporting requirements under TSCA; announced a new general practice of reviewing confidential business information claims under TSCA; mandated that manufacturers of 19 chemicals or large volume conduct testing and provide data to the agency using TSCA authority; drafted multiple chemical action plans; and stepped up efforts to regulate articles under TSCA. Based on these and other examples, it would appear that part of the problem with TSCA is that a number of its authorities have not been utilized rather than the law itself lacking the necessary "tools". Are there other authorities in TSCA currently not being used? Are there authorities that have been hindered by legal decisions or interpretations that could be clarified with simple legislation?

5. If TSCA was reformed to mandate the testing of all chemicals in commerce, new and old, how would EPA deal with the massive new administrative burden? How could the agency ensure that chemicals are reviewed in a timely enough manner not to stifle innovation and hurt industries? How could EPA ensure that all the new testing required would be done accurately using the best available science?

6. Would there be meaningful public health benefits or environmental gains if EPA created a minimum data set for chemicals that have been extensively studied and toxicity and exposure levels are well-known?

7. A comparison is often made between TSCA and laws such as FIFRA of FFDCA, which regulate pesticides, to highlight a perceived lack of proper authority and safety

standards to regulate chemicals. Isn't there a clear distinction in many cases between the products these laws regulate –TSCA regulating thousands of often innocuous chemicals used in everyday life—while FIFRA and FFDCA regulate products specifically manufactured to be, in many instances, poisonous? Doesn't it make sense to look at these categories of chemicals and products through different lenses?

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB - 3 2012

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Barbara Boxer
Chairman
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510-6175

Dear Chairman Boxer:

Thank you for the opportunity to respond to your August 3, 2011 letter and the questions for the record following the February 3, 2011 hearing on "Assessing the Effectiveness of U.S. Chemical Safety Laws." The attached document has responses to the questions. I hope that this information is useful to you and the members of the committee.

If you have any further questions, please contact me or your staff may call Sven-Erik Kaiser in my office at (202) 566-2753.

Sincerely,

Arvin Ganesan
Associate Administrator

Attachment

Senate Committee on Environment and Public Works
Subcommittee on Superfund, Toxics, and Environmental Health
Hearing on "Assessing the Effectiveness of U.S. Chemical Safety Laws"
February 3, 2011
Questions for the Record

Chairman Barbara Boxer, California

Boxer 1A. In 2009, the EPA initiated a chemical action plan for existing chemicals. Could you please describe the reasons for these plans, benefits of this type of action and any difficulties that the agency has experienced when developing and implementing the plans?

Answer: The EPA created the chemical action plans under the EPA's Enhanced Chemical Management approach announced by Administrator Lisa Jackson in September 2009. This announcement included the release of a set of administration principles to help guide Toxic Substances Control Act (TSCA) reform and a comprehensive approach to enhance the EPA's chemical management program using the agency's existing authorities under TSCA to achieve the following goals:

- Identify chemicals that pose significant risk and take action to address those risks;
- Obtain information to fill gaps in health and safety data on chemicals; and
- Make more information on chemicals transparent and accessible to the public.

In selecting chemicals for action plan development, the agency accessed readily available information on hazard, use, and exposure. The initial chemicals selected were chosen on the basis of multiple factors, including, among others:

- Chemicals identified as persistent, bio-accumulative, and toxic;
- High production volume chemicals;
- Chemicals in consumer products;
- Chemicals potentially of concern for children's health because of reproductive or developmental effects;
- Chemicals subject to review and potential action in international forums;
- Chemicals found in human bio-monitoring programs; and
- Chemicals in categories generally identified as being of potential concern in the new chemicals program.

Between December 2009 and April 2011, the EPA developed and made public ten Action Plans addressing various chemicals or groups of chemicals with potential risks to human health or the environment. The Action Plans summarize the potential risks from the chemicals and identify steps the agency may take to address those risks and/or gather additional data on the chemicals. These actions include a range of approaches under TSCA including requiring the submittal or development of data needed to help assess risks under TSCA Sections 4 and 8, requiring notification to the EPA under Section 5 before new uses of the chemicals that might increase

exposure and risk, and consideration of control measures under Section 6. The Action Plans also consider identification of safer alternatives to some of the high risk chemicals and uses.

Boxer 1B. Please also describe:

A. How the creation of these plans and the generation of information resulting from these plans can be expedited;
B. Any gaps in information needed to protect public health that may remain following the completion of these plans; and
C. Whether this type of information, and any additional information, should generally be provided for other chemicals, including new chemicals if the Toxic Substances Control Act is modified during reauthorization.

Answer: While the EPA is moving as expeditiously as possible to develop rules using current TSCA authorities to the greatest extent possible to develop the actions necessary to address the risks identified in the Action Plans, the EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns.

The Administration Principles released in 2009 broadly outline the tools the EPA needs, such as data call in, to quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals. Manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support review by the agency. Exposure and hazard assessments from manufacturers should be required to include a thorough review of risks to sensitive subpopulations. The EPA's authority to require submission of use and exposure information should extend to downstream users of chemicals.

Clear, enforceable and practicable deadlines applicable to the agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive subpopulations. The EPA should have the authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations.

Outlined below is the complete set of the Administration Principles for TSCA Reform:

1. **Chemicals Should Be Reviewed Against Safety Standards That Are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment.**

   The EPA should have clear authority to establish safety standards that are based on scientific risk assessments. Sound science should be the basis for the assessment of chemical risks, while recognizing the need to assess and manage risk in the face of uncertainty.

2. **Manufacturers Should Provide the EPA With the Necessary Information to Conclude That New and Existing Chemicals Are Safe and Do Not Endanger Public Health or the Environment.**

   Manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support a determination by the agency that the chemical meets the safety

standard. Exposure and hazard assessments from manufacturers should be required to include a thorough review of the chemical's risks to sensitive subpopulations. Where manufacturers do not submit sufficient information, the EPA should have the necessary authority and tools, such as data call in, to quickly and efficiently require testing or obtain other information from manufacturers that are relevant to determining the safety of chemicals. The EPA should also be provided the necessary authority to efficiently follow up on chemicals which have been previously assessed (e.g., requiring additional data or testing, or taking action to reduce risk) if there is a change which may affect safety, such as increased production volume, new uses or new information on potential hazards or exposures. The EPA's authority to require submission of use and exposure information should extend to downstream processors and users of chemicals.

3. **Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations.**

   The EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns.

4. **Manufacturers and the EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner.**

   The EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable and practicable deadlines applicable to the agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive subpopulations.

5. **Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened.**

   The design of safer and more sustainable chemicals, processes, and products should be encouraged and supported through research, education, recognition, and other means. The goal of these efforts should be to increase the design, manufacture, and use of lower risk, more energy efficient and sustainable chemical products and processes.

   TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI). Manufacturers should be required to substantiate their claims of confidentiality. Data relevant to health and safety should not be claimed or otherwise treated as CBI. The EPA should be able to negotiate with other governments (local, state, and foreign) on appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety.

6. **The EPA Should Be Given a Sustained Source of Funding for Implementation.**

   Implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that the EPA is meeting that goal. To that end, manufacturers of chemicals should support the costs of agency implementation, including the review of information provided by manufacturers.

Additionally, the EPA is taking steps to implement various items outlined in the Action Plans. Those proposals are currently undergoing interagency review.

Boxer 2: In 2008, the EPA issued a safeguard to address the threats to human health, including children's health, from lead chips and dust during and following renovation and repair work. Please describe the expected benefits of the agency's implementation of the Lead, Repair and Renovation safeguards, how implementation is progressing, and the steps that the agency has taken to ease implementation for small businesses.

Answer: Exposure to lead paint (above 5 ug/dL) affects over one million children today, with children under the age of six at the greatest risk. The benefits of the rule result from the prevention of adverse health effects attributable to lead exposure. Neurotoxic effects in children and cardiovascular effects in adults are known to occur at very low blood-lead concentrations (at or below 5 to 10 μg/dL). These categories of effects are and the potential effect levels are well substantiated and currently of greatest public health concern.

The EPA promulgated the Lead Renovation, Repair and Painting (LRRP) rule in 2008 pursuant to the requirements of the Residential Lead-Based Paint Hazard Reduction Act of 1992 to help reduce potential exposure to lead-based paint hazards, including toxic lead paint dust, created by renovation activities. In 2010 the LRRP was amended to cover all pre-1978 housing, making it more protective.

As of September 21, 2011, the EPA has accredited 573 training providers (including 346 traveling trainers) who have conducted more than 34,000 classes, training an estimated 725,000 people in the construction and remodeling industries to use lead-safe work practices. The EPA has approved 92,631 firms (110,460 firms including those approved by authorized states).

The Agency has taken many steps to ease implementation for small businesses. Prior to developing the proposed rule, the EPA organized a Small Business Advocacy Review (SBAR) panel, which included representatives from the EPA, the Small Business Administration, and the Office of Management and Budget. The SBAR panel consulted with small entities on cost and economic implications of the proposed regulation for small entities. As a result of this consultation with small businesses, the EPA sought a quick, inexpensive, reliable, and easy to perform alternative to a requirement for laboratory lead-dust testing ("clearance") as a means of determining that the renovation job was complete. The LRRP rule's cleaning verification process ensures that leaded dust created by renovations is adequately cleaned up without the expense and time required for laboratory testing.

Also, the LRRP rule was finalized in 2008, and allowed two years before the rule became fully effective and renovators were required to follow the work practices. To further assist small businesses who expressed concern about their ability to obtain worker training and the EPA certification, shortly after the rule became effective the EPA provided renovation firms and workers additional time to obtain the necessary training and certification in order to comply with the new rule. The rule also allows for flexibility in a number of areas that should be particularly helpful to small businesses; for example, certified renovators are not required to be on site at all times. Additional flexibility is provided by allowing on the job training to allow for hiring flexibility (e.g., temporary/day laborers). In the first year of the program, the EPA's focus has been on compliance assistance, rather than penalty enforcement. In addition, the EPA also issued a regulation as part of the recent amendments to the LRRP rule, which became effective

on October 5, 2011, that allows renovators the flexibility of taking paint chip samples as another method of determining the presence of lead-based paint.

Ranking Member James M. Inhofe, Oklahoma

Inhofe 1. Please describe your view of the "new chemicals program." Does the program allow companies to send dangerous chemicals into the stream of commerce without any controls or restrictions?

Answer: The EPA believes that the new chemicals program has effectively used the tools available under TSCA to allow the agency to review new chemicals prior to introduction into the marketplace. The EPA's New Chemicals Program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. The program functions as a "gatekeeper" that can identify conditions, up to and including a ban on production, to be placed on the use of a new chemical before it is entered into commerce. Anyone who plans to manufacture or import a new chemical substance for a nonexempt commercial purpose is required by section 5 of TSCA to provide the EPA with notice before initiating the activity. Because of limitations in the data generally available for new chemicals, it is possible that some health risks to workers, consumers, and the general population as well as ecological risks to aquatic and terrestrial organisms may not be identified during premanufacture reviews. TSCA does not require a safety determination for new chemicals, except for exemptions under TSCA section 5(h)(4).

Inhofe 2. Could you describe what information is required to be submitted under the new chemicals program when a company submits a premanufacture notice? After this information is submitted to the agency, does the EPA analyze it or conduct any sort of assessment? If so, after an assessment is conducted, does the EPA have the ability to prohibit or limit manufacture of the substance or ask the company to develop and submit additional data?

Answer: Premanufacture notices (PMNs) and exemption applications must include information such as specific chemical identity, use, anticipated production volume, exposure and release information, and any existing test data in the control or possession of the notice submitter. TSCA does not require that new chemical notices accompanied by basic hazard, exposure, and use data that would allow the agency to make a positive determination that a new chemical will not present an unreasonable risk of injury to health or the environment. However, as explained in the following paragraphs, the EPA can require the development of such information by the submitter of the PMN if the EPA makes certain determinations under TSCA Section 5(e).

Based on the information provided, PMNs and exemption applications are reviewed by the EPA to evaluate whether the substance may present an unreasonable risk of injury to human health or the environment or whether the substance, if produced in substantial quantities, may be anticipated to enter the environment in substantial quantities or result in substantial or significant exposure to the substance.

The EPA can take regulatory action under TSCA section 5(e) or section 5(f) to prohibit or limit the manufacture, processing, distribution in commerce, use, and disposal of a new chemical substance if the EPA determines that:

- There is insufficient information to evaluate the human health and environmental effects of the substance; and
- The substance may present (section 5(e)) or will present (section 5(f)) an unreasonable risk of injury to human health or the environment; or

- The substance will be produced in substantial quantities and may be anticipated to enter the environment in substantial quantities or there may be significant or substantial human exposure.

In such cases, section 5(e) orders are almost always issued as consent orders that are signed by both the EPA and the chemical manufacturer. Given the insufficient information finding, most section 5(e) orders require the PMN submitter to develop and submit to the EPA certain toxicity or fate tests before exceeding a specified production volume ("test trigger") designed to allow sales of the chemical to generate enough revenue to pay for the testing. Exposure-based section 5(e) orders consist primarily of a requirement to conduct triggered testing (plus recordkeeping and "risk notification" in case the test data indicates a risk.) Risk-based section 5(e) orders, depending on the type of concerns identified by the EPA for a given PMN substance, typically also require exposure controls such as gloves, goggles, respirators, specified disposal technologies or restrictions on releases to water, and hazard communication such as material safety data sheets (MSDS), labels, and training. The EPA typically issues Significant New Use Rules (SNURs) for PMNs with risk-based consent orders to ensure that other future manufacturers and processors of chemicals under consent orders are subject to the same terms and conditions of the consent order.

The EPA also has the authority to issue SNURs without a §5(e) Consent Order if the EPA determines that activities other than those described in the PMN may result in significant changes in human exposure or environmental release levels and/or that concern exists about the substance's health or environmental effects. SNURs typically identify testing that the EPA recommends be submitted with any SNUN to enable the EPA to better evaluate the potential risks associated with a new use.

Inhofe 3. If the agency is able to make either of these findings based on the available information, the EPA may take action under TSCA section 5(e) to prohibit or limit the manufacture, processing, distribution in commerce, use, and disposal of a new chemical substance, pending the development of additional information. How is the EPA striking the proper balance between protecting confidential business information and providing the public with information they need?

Answer: Over the past two years, the EPA has taken a number of significant steps to increase the public's access to chemical information and increase transparency by reducing unwarranted claims of confidentiality. For example, on November 28, 2011, the EPA announced that the agency has made publicly available hundreds of studies on chemicals that had previously been

treated as Confidential Business Information (CBI). These efforts are part of the EPA's efforts to make public chemical information that is not entitled to CBI status.
The EPA's efforts to promote transparency in no way affect how legitimate CBI is handled or protected by the EPA. The agency has long established, well developed processes for the management and handling of all materials claimed by submitters as CBI and regulations which implement TSCA section 14 (disclosure of data). CBI may only be declassified through the regulatory processes provided at 40 CFR Part 2 and also the TSCA specific regulations at 40 CFR 700 et seq. A copy of the November 28, 2011 announcement can be found at: http://yosemite.epa.gov/opa/admpress.nsf/a543211f64e4d199852573590040442/5b93eda1f3ee7bba852579510075728f!OpenDocument.

Inhofe 3A. With six IRIS risk assessments currently being delayed and reviewed due to concerns over the lack of "scientific integrity," what steps has the EPA taken to ensure that chemicals are properly reviewed using the best available science to get accurate and unbiased results?

Answer: In June 2010, the EPA became aware of the results of a report written by the National Toxicology Program (NTP), a program administered by the National Institute of Environmental Health Sciences (NIEHS), which outlined a review of research completed by the Ramazzini Institute, a lab in Italy that conducts animal testing to evaluate the potential cancer-causing effects of chemicals. The report discussed findings from an NTP assessment of an animal study on methanol and recommended that further pathology reviews by carried out to resolve differences of opinion between NTP scientists and the Ramazzini Institute in the diagnoses of certain cancers reported in the study.

To ensure the highest level of scientific integrity in its work, the EPA undertook a thorough review of all ongoing and previous chemical assessments to determine which, if any, relied substantially on cancer testing from the Ramazzini Institute. The EPA found six assessments, four of which were in draft form, that relied substantially on Ramazzini data. The four draft assessments are methanol, methyl tertiary-butyl ether (MTBE), ethyl tertiary-butyl ether (ETBE), and acrylonitrile, and the two final assessments are vinyl chloride and 1,1-dichloroethylene. Out of an abundance of caution, in the spirit of scientific integrity, and to ensure the agency's chemical assessments are grounded in the soundest possible science, the EPA placed the four draft assessments on hold pending further review.

In April 2011, the EPA announced its plan for addressing the four draft Integrated Risk Information System (IRIS) assessments that were placed on hold in June 2010, pending a review of some of the underlying studies relied on in the assessments.

The EPA and the NIEHS decided to jointly sponsor an independent Pathology Working Group (PWG) review of selected studies, including the methanol cancer assessment study on which the original NTP report was based. The review is nearing completion. The results will be made public and the four draft assessments will remain on hold until its completion.

The EPA will evaluate the results of the PWG review to inform conclusions about Ramazzini Institute tumor findings for the four draft assessments and two final assessments. These steps

will ensure that the agency is basing its assessments on the best possible scientific information and adhering to the strongest principles of scientific integrity.

Inhofe 4. Many advocates of TSCA reform, including the EPA, argue regularly that the current TSCA law does not "provide the tools" necessary "to adequately protect human health and the environment." Recently, the EPA has drafted an "Inventory Update Reporting" rule to expand industries reporting requirements under TSCA; announced a new general practice of reviewing confidential business information claims under TSCA; mandated that manufacturers of 19 chemicals or large volume conduct testing and provide data to the agency using TSCA authority; drafted multiple chemical action plans; and stepped up efforts to regulate articles under TSCA. Based on these and other examples, it would appear that part of the problem with TSCA is that a number of its authorities have not been utilized rather than the law itself lacking the necessary "tools". Are there other authorities in TSCA currently not being used? Are there authorities that have been hindered by legal decisions or interpretations that could be clarified with simple legislation?

Answer: Current TSCA authorities place legal and procedural requirements on the EPA before the agency can request the generation and submission of health and environmental effects data on existing chemicals, and take regulatory action. It has also proven difficult in some cases to take action to limit or ban chemicals found to cause unreasonable risks to human health or the environment. Even if the EPA has substantial data and wants to protect the public against known risks, the law creates obstacles to quick and effective regulatory action. For example, in 1989, after years of study and nearly unanimous scientific opinion about the risk, the EPA issued a rule phasing out most uses of asbestos in products. Yet, a federal court overturned most of this action because it found the rule had failed to comply with the requirements of TSCA. To date, the EPA has only been able to require testing on just more than 200 of the 84,000 chemicals listed on the TSCA Inventory, and has regulated or banned five of these chemicals under Section 6 of TSCA.

Nonetheless, the EPA has a responsibility to do all that it can under current authority to assess chemicals and take appropriate action to protect human health and the environment. The EPA is attempting to utilize the array of tools under TSCA to gather adequate data on and address any potential risks presented by chemicals. TSCA needs to be updated to increase confidence that chemicals used in commerce, which are vital to our Nation's economy, are safe and do not endanger the public health and welfare of consumers, workers, and especially sensitive sub-populations such as children, or the environment.

This much needed legislative reform should give the EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals.

Inhofe 5. If TSCA was reformed to mandate the testing of all chemicals in commerce, new and old, how would the EPA deal with the massive new administrative burden? How could the agency ensure that chemicals are reviewed in a timely enough manner not to stifle innovation and hurt industries? How could the EPA ensure that all the new testing required would be done accurately using the best available science?

Answer: It is difficult to fully determine the impact that a new bill will have on the EPA's ability to address new mandates.

The Administration Principles for TSCA Reform state that chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment, and that the EPA should have clear authority to establish safety standards that are based on scientific risk assessments. Further, manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support a determination by the agency that the chemical meets the safety standard. Where manufacturers do not submit sufficient information, the principles state that the EPA should have the necessary authority and tools, such as data call in, to quickly and efficiently require testing or obtain other information from manufacturers that are relevant to determining the safety of chemicals. Clear, enforceable and practicable deadlines applicable to the agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive subpopulations.

The principles also state that the EPA should be given a sustained source of funding for implementation in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that the EPA is meeting that goal.

Inhofe 6. Would there be meaningful public health benefits or environmental gains if the EPA created a minimum data set for chemicals that have been extensively studied and toxicity and exposure levels are well known?

Answer: Currently, the EPA lacks basic information on the potential health and environmental effects of many chemicals. While chemicals which demonstrate high toxicity and result in exposure above levels of concern should obviously be the focus of risk management efforts, one of the challenges the proposed legislation is seeking to address is a lack of available data needed to determine which chemicals are safe at current use levels and which should have controls in place. Rectifying this lack of data is an important goal of TSCA reform legislation.

Different classes and categories of chemicals may require different data sets, given differing characteristics and uses. Input from interested parties will help identify the requirements which should be put in place. If required data exist, the EPA would seek to avoid duplication and redundant reporting.

Inhofe 7. A comparison is often made between TSCA and laws such as FIFRA or FFDCA, which regulate pesticides, to highlight a perceived lack of proper authority and safety standards to regulate chemicals. Isn't there a clear distinction in many cases between the products these laws regulate –TSCA regulating thousands of often innocuous chemicals used in everyday life—while FIFRA and FFDCA regulate products specifically manufactured to be, in many instances, poisonous? Doesn't it make sense to look at these categories of chemicals and products through different lenses?

Answer: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) provide the federal government with effective authority to require manufacturers to provide the data necessary for review and approval as well as effective authority to remove risky products from the marketplace. The EPA recognizes that not all chemicals should be subject to the same level of scrutiny or regulation but it is important that

these chemicals be evaluated using the best available data and a more complete understanding of the exposure pathways and scenarios. It is also important that the EPA have the regulatory tools it needs to determine if these chemicals are being used safely as well as the ability to take action if they are not. The EPA has effectively implemented FIFRA and FFDCA and applied the safety standards set forth in those statutes for many years.

AL 11-000-0712

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510-6175

December 21, 2010

The Honorable Lisa Jackson
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

Dear Administrator Jackson:

Thank you for appearing before the Committee on Environment and Public Works on October 26, 2010. We appreciate your testimony, and we know that your input will prove valuable as we continue our work on this important topic.

Enclosed are questions that have been submitted by Senators Boxer and Inhofe for the hearing record. Please submit your answers to these questions by COB January 4, 2011 to the attention of Heather Majors, Senate Committee on Environment and Public Works, 410 Dirksen Senate Office Building, Washington, D.C. 20510. In addition, please provide the Committee with a copy of your answers via electronic mail to Heather_Majors@epw.senate.gov. To facilitate the publication of the record, please reproduce the questions with your responses.

Again, thank you for your assistance. Please contact Grant Cope of the Majority Staff at (202) 224-8832, or Dimitri Karakitsos of the Minority Staff at (202) 224-6176 with any questions you may have. We look forward to reviewing your answers.

Sincerely,

Barbara Boxer
Chairman

James M. Inhofe
Ranking Member

Environment and Public Works Committee Hearing
October 26, 2010
Follow-Up Questions for Written Submission

Questions for Administrator Jackson

Questions from:

Senator Barbara Boxer

1. The Benefits of Strengthening the Public's Right to Know About Dangerous Chemicals

   A. Does the Agency support greater public transparency on chemical risk management decisions?

   B. If so, what are the potential benefits to consumers, responsible chemical manufactures, protections for the health of pregnant women and children and others that the Agency foresees from such transparency?

2. The Benefits of Straightforward Safety Information From Chemical Manufacturers

   A. Does the Agency support manufacturers providing straightforward information that demonstrates their chemicals are safe when used by families, in schools and workplaces and in other settings in our country?

   B. If so, what are the potential benefits to consumers, responsible chemical manufactures, protections for the health of pregnant women and children and others that the Agency foresees from such straightforward information?

   C. The European Union is currently implementing its modernization of safeguards that are designed to protect public health from dangerous chemicals, including requiring chemical manufacturers and downstream users of such chemicals to provide information on such chemicals.

      i. Is the Agency fully briefed the E.U. activities?

      ii. Will the Agency have access to the information that the E.U. is collecting?

      iii. If EPA will have such access, will the Agency be able to use that information, and to share information relevant to protecting human health and environmental quality with state and local governments and individuals who work to protect public health?

3. High Costs and Inefficiencies of Current Chemical Regulation Authorities

   A. What administrative burdens and costs, including costs borne by U.S. taxpayers, does the Corrosion Proof Fittings v. EPA court decision raise to EPA's

ability to restrict the production and use of chemicals that present risks to public health?

Senator James M. Inhofe

1. During the hearing, you discussed some of the benefits of TSCA reform, which you said would in some cases be felt immediately. Has EPA examined the potential negative economic impacts of reform from the increased burden of minimum data requirements, costs and difficulties of product and chemical replacement, and unintended consequences associated with replacement chemicals?

2. In your written testimony, you complain that "TSCA does not have a mandatory program where EPA must conduct a review to determine the safety of existing chemicals." Yet if EPA had a mandatory program for every chemical in commercial use, would you agree that such a program could impose serious economic impacts, massive administrative burdens, without providing meaningful public health benefits or environmental gains?

3. During your tenure you have said that evaluating the safety of chemicals should be based on risk, meaning a combination of the toxicity of a chemical and exposure. Given that statement, why is the agency spending its limited resources on BPA, a chemical with very low exposure to humans?

4. Considering EPA has acknowledged it (probably) lacks the resources necessary to study chemicals already scheduled for new assessments, why has the agency now chosen to seek nominations for new risk studies for the agency's IRIS database? What is the projected timetable for assessing newly nominated chemicals when the agency cannot complete the currently scheduled risk assessments?

5. EPA is currently "holding" four pending IRIS assessments and "reviewing" two published assessments in part because of questions of scientific integrity. In the event that the agency's chemical workload increases significantly over time, how would it ensure that it utilizes the best available science?

6. Proponents of TSCA reform point to EPA's experience with asbestos as justification for advancing TSCA reform legislation. The U.S. Fifth Circuit Court of Appeals in the *Corrosion Proof Fittings v. Environmental Protection Agency* did not hold that asbestos could not be regulated under TSCA. Do you agree with that interpretation of the court's ruling?

   A. Is it correct that the court also did not overturn EPA's total ban on asbestos, that it simply issued an order to vacate and remand the rule to EPA for further review?

   B. The court found that EPA failed to give proper notice of methodology in adopting analogous exposure estimates during the final weeks of the rulemaking process after public comment was concluded, and that EPA denied cross-examination of some of its witnesses. Do you believe that giving proper notice for an informed comment period and allowing cross-examination of witnesses is important protocol for EPA to follow?

C. Do you agree that the decision did not prohibit EPA from going back and attempting to correct the errors in the rule-making that the court identified?

D. Is it your view that EPA's decision not to re-propose the asbestos rule was an agency policy decision, and not one ordered by the court?

Questions for the Record, Questions for Administrator Jackson
TSCA Field Hearing

Questions from:
Senator Barbara Boxer

1. The Benefits of Strengthening the Public's Right to Know About Dangerous Chemicals

A. Does the Agency support greater public transparency on chemical risk management decisions?

Response: EPA is committed to providing the public with greater access to chemical information and over the last 18 months has taken a number of significant actions to increase transparency. These efforts include new policies to limit claims for confidentiality on critical health and safety data, increased and easier web access to a wide range of chemical-specific information (including the Chemical Access Data Tool, a searchable data base), and working with the U.S. chemical industry to reduce confidentiality claims that are overly broad or no longer needed to protect business needs. These actions will also provide the public with a greater understanding of the chemicals on which EPA is taking action.

Also, as the Administration's principles for legislative reform indicate, provisions assuring transparency and public access to information should be strengthened. Specifically, *TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI and manufacturers should be required to substantiate their claims of confidentiality. Also, data relevant to health and safety should not be claimed or otherwise treated as CBI. Finally, EPA should be able to negotiate with other governments (local, state, and foreign) on appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety.*

B. If so, what are the potential benefits to consumers, responsible chemical manufactures, protections for the health of pregnant women and children and others that the Agency foresees from such transparency?

Response: A substantial increase in information available on toxic chemicals could provide the public with a greater understanding of the chemicals on which EPA is taking action, and help enable State, tribal and local governments and the public to make better informed decisions about the chemicals that are in the products consumers use daily. Manufacturers have an important interest in ensuring public confidence both in the regulation of chemicals and in the safety of their products, as well as continuing innovation in the development and use of safer alternatives. As part of EPA's efforts to increase the public's access to chemical information, EPA has taken a series of significant steps over the past 18 months to empower the public with greater access to critical information on the chemicals manufactured and used in this country. Additional information on these actions can be found at: http://www.epa.gov/oppt/existingchemicals/pubs/transparency.html.

2. The Benefits of Straightforward Safety Information from Chemical Manufacturers

A. Does the Agency support manufacturers providing straightforward information that demonstrates their chemicals are safe when used by families, in schools and workplaces and in other settings in our country?

Response: Yes, as stated in the Administration principles on TSCA Reform, EPA believes the responsibility to provide adequate health and safety information should rest on industry. EPA believes manufacturers should be required to develop and submit the hazard, use, and exposure data demonstrating that new and existing chemicals are safe. If industry doesn't provide the information, EPA believes it should have the necessary tools to quickly and efficiently require testing, or obtain other information from manufacturers that are relevant to determining the safety of chemicals.

B. If so, what are the potential benefits to consumers, responsible chemical manufactures, protections for the health of pregnant women and children and others that the Agency foresees from such straightforward information?

Response: A substantial increase in information available on toxic chemicals could improve the understanding of chemical risks and greatly enable government and the public to make better informed decisions about the chemicals that are in the products consumers use daily. Manufacturers have an important interest in ensuring public confidence both in the regulation of chemicals and in the safety of their products, as well as continuing innovation in the development and use of safer alternatives.

C. The European Union is currently implementing its modernization of safeguards that are designed to protect public health from dangerous chemicals, including requiring chemical manufacturers and downstream users of such chemicals to provide information on such chemicals.

I. Is the Agency fully briefed the E.U. activities?

Response: Yes. In fact, EPA and the European Chemicals Agency (ECHA) recently signed a Statement of Intent designed to enhance technical implementation of each country's chemicals management programs by sharing information, approaches, and experience.

II. Will the Agency have access to the information that the E.U. is collecting?

Response: According to the EU's Registration Evaluation and Authorization of Chemicals (REACH) Regulation, the European Community's regulation on chemicals and their safe use, much of the information that ECHA receives will be publicly available. There is also a mechanism under REACH for the disclosure of confidential information. EPA will explore how the Agency can utilize this mechanism.

III. If EPA will have such access, will the Agency be able to use that information, and to share information relevant to protecting human health and environmental quality with state and local governments and individuals who work to protect public health?

Response: EPA will be able to use the information provided by ECHA or otherwise available under REACH. EPA's ability to share the information with state and local governments and other individuals will have to be determined on a case-by-case basis, depending on whether the information is claimed confidential, and the application of U.S. confidentiality laws to any such claims.

3. High Costs and Inefficiencies of Current Chemical Regulation Authorities

A. What administrative burdens and costs, including costs borne by U.S. taxpayers, does the Corrosion Proof Fittings v. EPA court decision raise to EPA's ability to restrict the production and use of chemicals that present risks to public health?

Response: EPA has previously stated that the agency believes it has proven difficult in some cases to exercise the full scope of its discretion to limit or ban chemicals found to cause unreasonable risks to human health or the environment. Even if EPA has substantial data and wants to protect the public against known risks, EPA believes TSCA creates obstacles to quick and effective regulatory actions. The chief significance of the Corrosion Proof Fittings case consists of the court's interpretation of the analytical requirements to issue a chemical control rule under section 6 of TSCA. Since section 6 is the most significant mechanism to mitigate risk under TSCA, the court's interpretation has programmatic ramifications that extend well beyond the case's immediate impact on the Agency's ability to regulate asbestos. Specifically, the court reviewed EPA's cost -benefit analysis in light of the statutory requirement under TSCA section 6 that EPA seek the least burdensome regulation..

Senator James M. Inhofe

1. During the hearing, you discussed some of the benefits of TSCA reform, which you said would in some cases be felt immediately. Has EPA examined the potential negative economic impacts of reform from the increased burden of minimum data requirements, costs and difficulties of product and chemical replacement, and unintended consequences associated with replacement chemicals?

Response: EPA has not done an economic analysis of proposed legislation. We believe, however, that an appropriate balance can be achieved between the economic impacts and the need to ensure the American public that the chemicals they and their families are exposed to are safe. In fact, a credible Federal program will increase consumer confidence and encourage firms that innovate to produce safer products.

2. In your written testimony, you complain that "TSCA does not have a mandatory program where EPA must conduct a review to determine the safety of existing chemicals." Yet if EPA had a mandatory program for every chemical in commercial use, would you agree that such a program could impose serious economic impacts, massive administrative burdens, without providing meaningful public health benefits or environmental gains?

Response: EPA recognizes that prioritization will be an important element of a reformed chemicals management program. Conducting a comprehensive safety assessment on all

chemicals listed on the TSCA inventory would be challenging, even with increased resources. It will be necessary for new legislation to provide EPA with sustained resources and flexibility in determining what factors should be considered in prioritizing chemicals for review and to take into account a range or considerations, including children's health, economic costs, social benefits, and equity concerns.

3. During your tenure you have said that evaluating the safety of chemicals should be based on risk, meaning a combination of the toxicity of a chemical and exposure. Given that statement, why is the agency spending its limited resources on BP A, a chemical with very low exposure to humans?

   Response: In January, 2010, the U.S. Food and Drug Administration (FDA) announced that it has some concerns about the potential human health impacts of bisphenol A (BPA) and has additional studies underway to more fully understand those concerns. While these studies are underway, EPA is focusing its efforts on the environmental concerns associated with the potential effects of BPA in aquatic species. This may include testing or monitoring data in the vicinity of landfills, manufacturing facilities, or similar locations to determine the potential for BPA to enter the environment at levels of potential concern for human and environmental exposures. On March 29, 2010, EPA released an action plan on BPA that outlines a range of actions that EPA is considering to address these potential environmental concerns. The action plan can be found at http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/bpa.html.

4. Considering EPA has acknowledged it (probably) lacks the resources necessary to study chemicals already scheduled for new assessments, why has the agency now chosen to seek nominations for new risk studies for the agency's IRIS database? What is the projected timetable for assessing newly nominated chemicals when the agency cannot complete the currently scheduled risk assessments?

   Response: The Federal Register notice that EPA published on October 18, 2010 requesting nominations from the public for substances to be considered for an assessment or reassessment in the IRIS Program is an important outreach to the public that is conducted by the Agency on a regular basis. It illustrates EPA's commitment to public participation and EPA's responsiveness to the needs of the public in helping to shape the IRIS agenda. While there are approximately 70 assessments currently underway in the IRIS program, any nominations that are submitted as a result of this public outreach will be evaluated for inclusion in the 2011 agenda. The chemical assessment nominations selected will go into the IRIS assessment queue or pipeline as other assessments are completed and posted on the IRIS Web site. This past fiscal year ten completed assessments were posted on IRIS. It is essential to plan for the development of IRIS assessments several years in advance to ensure a continuous pipeline of assessments in the IRIS program.

5. EPA is currently "holding" four pending IRIS assessments and "reviewing" two published assessments in part because of questions of scientific integrity. In the event that the agency's chemical workload increases significantly over time, how would it ensure that it utilizes the best available science?

Response: On June 15, 2010 EPA issued the press release, 'EPA Places Four IRIS Assessments on Hold Pending Review' referring to the assessments for methanol, MTBE, ETBE and acrylonitrile. The release stated, "EPA is holding these assessments due to a report from the National Toxicology Program (NTP) that outlines a recent review of a research study completed by the Ramazzini Institute, a lab in Italy that conducts animal testing to evaluate the potential cancer-causing effects of chemicals. The report discusses findings from a recent assessment by NTP pathologists of an animal study on methanol. NTP's report recommends that further pathology reviews be carried out to resolve differences of opinion between NTP scientists and the Ramazzini Institute in the diagnoses of certain cancers reported in the study. Out of an abundance of caution and to ensure the agency's chemical assessments are grounded in the soundest possible science, EPA undertook a thorough review of all ongoing and previous chemical assessments to determine which, if any, relied substantially on cancer testing from the Ramazzini Institute."

It is anticipated that the number and type of health assessments for chemical contaminants will increase with time as indicated. The Agency will continue to evaluate relevant data prior to its use in IRIS health assessments to ensure the highest degree of scientific integrity. The IRIS Program relies on the expertise of scientists from within the program and across the Agency to evaluate the available scientific literature and conducts rigorous expert peer reviews to obtain an independent evaluation of the scientific work of the Agency. http://yosemite.epa.gov/opa/admpress.nsf/03dd877d6f1726c28525735900404443/b64d44f06a56d5b285257742007c5002!OpenDocument.

6. Proponents of TSCA reform point to EPA's experience with asbestos as justification for advancing TSCA reform legislation. The U.S. Fifth Circuit Court of Appeals in the *Corrosion Proof Fittings v. Environmental Protection Agency* did not hold that asbestos could not be regulated under TSCA. Do you agree with that interpretation of the court's ruling?

   A. Is it correct that the court also did not overturn EPA's total ban on asbestos, that it simply issued an order to vacate and remand the rule to EPA for further review?
   B. The court found that EPA failed to give proper notice of methodology in adopting analogous exposure estimates during the final weeks of the rulemaking process after public comment was concluded, and that EPA denied cross-examination of some of its witnesses. Do you believe that giving proper notice for an informed comment period and allowing cross-examination of witnesses is important protocol for EPA to follow?
   C. Do you agree that the decision did not prohibit EPA from going back and attempting to correct the errors in the rule-making that the court identified?
   D. Is it your view that EPA's decision not to re-propose the asbestos rule was an agency policy decision, and not one ordered by the court?

Response: While the court in the Corrosion Proof Fittings case did not order EPA not to re-propose an across-the-board ban of asbestos, EPA believes the court's reasoning altered the legal landscape regarding the type and quantity of analysis necessary to support a rulemaking under section 6 of TSCA. The chief significance of the Corrosion Proof Fittings case consists of the court's interpretation of the analytical requirements to issue a chemical

control rule under section 6. Since section 6 is the most significant mechanism to mitigate risk under TSCA, the court's interpretation has programmatic ramifications that extend well beyond the case's immediate impact on the Agency's ability to regulate asbestos.

Specifically, the court reviewed EPA's cost-benefit analysis in light of the statutory requirement under TSCA section 6 that EPA seek the least burdensome regulation. Asbestos remains subject to TSCA jurisdiction. The rule, however, was vacated in substantial part on the court's finding that "before it [EPA] impose a ban on a product, it first evaluate and then reject the less burdensome alternatives laid out for it by Congress" overturning those portions of the rule to which the vacatur applied. Other portions of the rule were not vacated and remain in effect, including the ban on new uses of asbestos.

The court also faulted the Agency on two purely procedural issues: the adequacy of public notice of the rulemaking and the availability of witness cross-examination in hearings associated with the rulemaking. EPA is committed to following all necessary procedural requirements associated with regulatory actions such as those mandated in the Administrative Procedure Act and various Executive Orders. Likewise, in the case of administrative hearings, EPA agrees that parties to a proceeding must be afforded the full range of procedural rights specified under governing law.